EXHIBIT J

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IN THE COURT OF COMMON PLEAS

OF PHILADELPHIA COUNTY, PENNSYLVANIA

TRIAL DIVISION - CIVIL

IN RE: PELVIC MESH LITIGATION: February 2014, No. 829

KATHRYN McGEE and MICHAEL

McGEE,

: JULY TERM, 2013

Plaintiffs,

vs.

: No. 003483

ETHICON WOMEN'S HEALTH AND UROLOGY, A DIVISION OF ETHICON, INC., et al.

Defendants. :

The deposition of BRUCE ALAN ROSENZWEIG, M.D., taken before Pauline M. Vargo, an Illinois Certified Shorthand Reporter, C.S.R. No. 84-1573, at the law offices of Wexler Wallace, LLP, Suite 3300, 55 West Monroe Street, Chicago, Illinois, on February 4, 2016, at 8:55 a.m.

> GOLKOW TECHNOLOGIES, INC. 877.370.3377 ph 917.591.5672 fax deps@golkow.com

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1 (The witness was duly sworn.) 2 BRUCE ALAN ROSENZWEIG, M.D., 3 called as a witness herein, having been first duly 4 sworn, was examined and testified as follows: 5 EXAMINATION 6 BY MR. ROSENBLATT: 7 Q. Good morning, Dr. Rosenzweig. 8 A. Good morning, sir. 9 Q. You have testified a number of times in 10 the pelvic mesh litigation, correct? 11 A. Correct. 12 Q. And so today your opinions are focused 13 on TVT Secur, is that correct? 14 A. Yes. 15 Q. So, would it be fair to say that we 16 could rely on your previous testimony in your 18 back and rehash a lot of those issues? 19 A. Yes. 10 you for your services? A. Mr. Waldenberger. 3 Q. And what did Mr. Waldenberger ask you to do on the McGee case? 4 A. Mr. Waldenberger. 5 A. To give opinions about the design, the development and the warnings associated with the TVT Secur. 6 Q. And how many hours did you spend looking into or formulating your opinions about the design development and warnings of TVT Secur? 11 A. Well, I have been working on TVT Secur? 12 D. So, would it be fair to say that we development and the warnings associated with the TVT Secur case, the Rabiola case in Texas, and I had been working on that for over a year. So, much of the information regarding the design, the development and the warnings associated with the TVT Secur I had already been reviewing for that other case. 19 Q. So when Mr. Waldenberger ask you to do on the McGee case? A. Mr. Waldenberger. Q. And what did Mr. Waldenberger ask you to do on the McGee case? A. To give opinions about the design, the development and warnings associated with the TVT Secur case, the Rabiola case in Texas, and I had been working on that for over a year. So, much of the information regarding the design, the development and the warnings associated with the TVT Secur I had already been reviewing for that other case. 19 Q. So when Mr. Waldenberger reached out to
BRUCE ALAN ROSENZWEIG, M.D., a called as a witness herein, having been first duly sworn, was examined and testified as follows: EXAMINATION BY MR. ROSENBLATT: Q. Good morning, Dr. Rosenzweig. A. Good morning, sir. Q. You have testified a number of times in the pelvic mesh litigation, correct? A. Correct. Q. And so today your opinions are focused on TVT Secur, is that correct? A. Yes. Q. So, would it be fair to say that we could rely on your previous testimony in your a called as a witness herein, having been first duly do on the McGee case? A. To give opinions about the design, the development and the warnings associated with the TVT Secur. D. And how many hours did you spend looki into or formulating your opinions about the design development and warnings of TVT Secur? A. Well, I have been working on TVT Secur for longer than that. I had been retained to work on a TVT Secur case, the Rabiola case in Texas, a 14 A. Yes. 15 Mr. Waldenberger. A. Mr. Waldenberger A. To give opinions about the design, the development and the warnings associated with the for longer than that. I had been retained to work on a TVT Secur case, the Rabiola case in Texas, a 14 I had been working on that for over a year. So, 15 much of the information regarding the design, the development and the warnings associated with the 16 could rely on your previous testimony in your 16 development and the warnings associated with the 17 TVT Secur I had already been reviewing for that other case.
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9 Q. You have testified a number of times in 10 the pelvic mesh litigation, correct? 11 A. Correct. 12 Q. And so today your opinions are focused 13 on TVT Secur, is that correct? 14 A. Yes. 15 Q. So, would it be fair to say that we 16 could rely on your previous testimony in your 17 depositions and your trials and we don't have to go 18 into or formulating your opinions about the design development and warnings of TVT Secur? 10 development and warnings of TVT Secur? 11 A. Well, I have been working on TVT Secur for longer than that. I had been retained to work on a TVT Secur case, the Rabiola case in Texas, a I had been working on that for over a year. So, much of the information regarding the design, the development and the warnings associated with the TVT Secur I had already been reviewing for that other case.
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14 A. Yes. 15 Q. So, would it be fair to say that we 16 could rely on your previous testimony in your 17 depositions and your trials and we don't have to go 18 back and rehash a lot of those issues? 14 I had been working on that for over a year. So, much of the information regarding the design, the development and the warnings associated with the TVT Secur I had already been reviewing for that other case.
Q. So, would it be fair to say that we 15 much of the information regarding the design, the could rely on your previous testimony in your 16 development and the warnings associated with the 17 depositions and your trials and we don't have to go 18 to the case.
16 could rely on your previous testimony in your 17 depositions and your trials and we don't have to go 18 back and rehash a lot of those issues? 19 development and the warnings associated with the TVT Secur I had already been reviewing for that other case.
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18 back and rehash a lot of those issues? 18 other case.
A. 1es. 19 Q. 30 when Mr. Waldenberger reached out to
MR. WALDENBERGER: Objection as to being overbroad, but you can answer the being overbroad, but you can answer the A. Well, again, most of, if not all, the
24 question. 24 information I had already reviewed. I had
Page 7
1 BY MR. ROSENBLATT: 1 depositions set for the Rabiola case that had been
2 Q. I guess what I'm getting at, do you 2 continued for approximately six or seven months
3 stand by all of your testimony to date? 3 So, the information that is contained in my exper
4 A. Yes. There might be one or two things 4 report I had already summarized not in report for
5 that I stated that could be corrected, but none 5 but in preparation form for depositions that had
6 that I specifically recall right now. 6 taken place long before I was contacted about th
7 Q. But each time you testified you were 7 case.
8 under oath? 8 Q. And so what material did you look at to
9 A. Correct. 9 formulate your opinions?
10 Q. But nothing you can think of today that 10 MR. WALDENBERGER: In general, y
11 you would need to change? 11 mean, with regard to the TVT-S?
12 A. Not specifically, no. 12 MR. ROSENBLATT: With regard to the
13 Q. When were you first retained to work on 13 TVT Secur.
14 the McGee case? 14 MR. WALDENBERGER: At any point
15 A. In December. 15 time?
16 Q. Would that be December of 2015? 16 MR. ROSENBLATT: Yes.
17 A. Yes. 17 A. Well, as you know, I have been reviewing
18 Q. Do you know if it was towards the 18 deposition testimony for four years now, give or
19 beginning of the month or the end of the month? 19 take. Much of that deposition testimony
20 A. Actually, it was right after 20 overlapped, whether it was for TVT, TVT-O, TV
Thanksgiving, so probably the end of November. 21 Abbrevo, and so the majority of the deposition
22 Q. And who retained you? 22 testimony I had already reviewed.
23 A. The Kline Specter law firm. 23 There was a lot of overlap between

3 (Pages 6 to 9)

Page 10 Page 12 1 I reviewed are outlined in my reliance list. 1 Q. Are you aware if there are more than 30 2 Q. And you mentioned your reliance list. 2 to 50 clinical studies evaluating TVT Secur? 3 3 That would contain internal documents, deposition A. There might be more, and again, there 4 testimony and literature; is that a fair 4 are meta-analyses that I've reviewed that would 5 5 summarization? encapsulate the majority of the literature. There 6 6 A. Correct. are things that I would look at. 7 7 Q. And it's important to create a reliance Again, there is probably more that I 8 8 list, in your opinion, correct? looked at that I briefly glanced over because they 9 9 A. Well, the reliance list is a list of might not have been as robust of a study as 10 10 materials that I've reviewed, and so it summarizes prospective randomized controlled trials are. So, 11 11 again, giving a brief number of the studies that the documents that I've reviewed for my opinions. 12 Q. And it also summarize the documents that 12 I've looked at, I mean, there are probably more 13 support your opinions, correct? 13 than that. 14 14 Q. Well, you would agree with me even if 15 15 Q. And it would be important to include all you have a meta-analysis or a Cochrane review, you, 16 16 of the documents in your reliance list that support Dr. Rosenzweig, still find it helpful to go back 17 your opinions about the TVT Secur, correct? 17 and review the underlying data that supports those 18 A. Yes. I think I've tried to incorporate 18 accumulated opinions, correct? 19 all the documents that I've relied on in my 19 A. Correct. 20 opinions. 20 Q. And did you do that in this case for the TVT Secur? 21 Q. And in formulating a reliance list to 21 22 support your opinions for the TVT Secur, you would 22 A. Yes. O. Of the 30 to 50 articles on TVT Secur 23 want to do a fair analysis of, for example, the 23 24 medical literature? 24 that you reviewed, did you include all of those on Page 11 Page 13 1 1 vour reliance list? A. Correct. 2 Q. And you would want to include on your 2 A. There might be some that might not be on 3 3 reliance list medical literature that would be both my reliance list, but I try to include everything 4 4 on my reliance list. good and bad for the Secur in order to provide a 5 5 Q. Did you have any type of criteria as far fair assessment, correct? 6 6 as whether or not you would include or exclude a A. Well, I've reviewed all the literature 7 7 regarding TVT Secur or, I would say, the vast certain study on TVT Secur? 8 8 majority of the literature regarding the TVT Secur, A. No. 9 both literature that would, as you say, supports my 9 Q. Did you formulate your reliance list, or 10 opinion and also literature that would -- I don't 10 was that prepared by counsel? MR. WALDENBERGER: Objection. Don't 11 think the term "contrary to my opinion" but that is 11 12 more favorable than the vast majority of the 12 answer. Under Pennsylvania law communications 13 13 literature on TVT Secur. between expert and lawyer regarding the 14 14 I think the literature on the TVT preparation of a report is privileged, so 15 Secur -- on the TVT Secur is quite evident that 15 don't answer. 16 there is a problem with its efficacy and there is a 16 Q. Your counsel has instructed you not to 17 problem with its safety. 17 answer the question. Are you going to answer the 18 Q. Now, you said you reviewed all of the 18 question? 19 literature on TVT Secur. How many clinical studies 19 A. No. 20 20 MR. WALDENBERGER: No, he is not going are there on TVT Secur? 2.1 21 to answer the question. Good try, though. A. The exact number I cannot give you. 22 Q. How did you obtain the 30 to 50 articles 22 Q. Can you give me a ballpark? 23 A. I would say I've reviewed, you know, 23 on TVT Secur that you reviewed? A. And again, that is just a rough 24 anywhere from 30 to 50 articles on TVT Secur. 2.4

Page 14 Page 16 TVT Secur to get a better understanding of the 1 estimation. There could be more. There might be 1 2 less. Through searches by looking at again 2 volume of clinical studies on TVT Secur? 3 3 A. Well, I think the volume of the clinical meta-analysis and looking at their reference list; 4 and that would be, you know, looking at papers and 4 studies would be reflected in not only the Cochrane 5 5 seeing what they referred to in their papers. That analysis but, you know, there are a number of 6 6 would be a way of getting at the literature that I studies, if you will, that were either -- could 7 7 either be considered like review articles and reviewed. 8 8 Q. Did you make any attempt to go back and opinion pieces that might not be as robust as the 9 9 perform any type of systematic literature review randomized control trials. 10 yourself on TVT Secur? 10 Q. Would it be important for you to look at 11 MR. WALDENBERGER: Objection, form, 11 case studies, case series and observational studies 12 12 on TVT Secur? vague. 13 You can answer if you understand. 13 A. Yes. I tried to look at case series, 14 A. I don't understand what you are talking 14 observational studies, retrospective analysis. 15 about, a systematic review. Again, I looked at --15 Q. You said there are approximately 30 to 16 16 50 articles on TVT Secur, just your ballpark range. Q. Strike the question. I will take out 17 the word "systematic." 17 How many of those 30 to 50 would you consider to be 18 Dr. Rosenzweig, did you make any attempt 18 randomized controlled trials as opposed to just a 19 to review -- or strike that. 19 20 20 How did you go about ensuring that you A. I think there is in the neighborhood of reviewed all of the relevant literature on TVT 21 21 20 to 30 randomized control trials on the TVT 22 Secur? 22 Secur 23 Q. Have you reviewed all 20 to 30 RCTs on 23 A. Well, again, I looked at the studies 24 that had been published. I looked at their 24 TVT Secur? Page 15 Page 17 1 references, looked at the meta-analysis, looked at 1 A. I have tried to, yes. 2 their references and continued to review studies 2 Q. You said you tried to. What efforts 3 3 have you made other than what you've previously that were done, did literature searches, and to 4 assure that I had reviewed the depth and the 4 discussed about looking at larger meta-analyses and 5 5 breadth on the subject of TVT Secur. performing an individual search for an individual 6 Q. Did you perform any searches yourself in 6 topic? 7 7 any type of medical journal database? A. Well, that would be one of the topics, 8 8 A. I have PubMed and access to searches on would be randomized control trials. 9 PubMed, and so yes, I would look at PubMed. Google 9 Q. So, when I previously asked you do you 10 Scholar is another nice search engine to find 10 recall which topics you specifically searched out, 11 11 scholarly literature, and so if there was a you didn't recall. Is it my understanding that you 12 specific topic on TVT Secur that I wanted to look 12 performed a specific search on RCTs for TVT Secur? 13 13 at, those would be the resources that I went to. A. Either specifically in that sense or 14 14 Q. And just so I can appreciate your looking at other sources for a list of the 15 testimony, you did in fact run some PubMed searches 15 randomized control trials for TVT Secur. So, I 16 on TVT Secur? 16 mean, that was one of the things that I wanted to 17 A. If there was something that I could not 17 see, is if I had looked at all or virtually all of find, then it would be for a specific topic on TVT 18 18 the randomized control trials on TVT Secur. 19 19 Q. And it would be important to you in 20 Q. And can you identify those specific 20 formulating your opinions on TVT Secur to look at 21 topics where you performed a PubMed search on TVT 21 as many or all of the RCTs and other clinical Secur? 22 studies on TVT Secur, correct? 22 23 A. Not that I specifically recall. 23 A. Correct. 24 Q. Did you perform a search in PubMed for 24 Because you wouldn't want to just look

5 (Pages 14 to 17)

Page 18 Page 20 1 at studies that showed bad results or bad cure 1 full-length midurethral slings. I would say an 2 rates or high complications, but you would want to 2 average objective cure would be in the range of 70, 3 3 75 percent or less. Subjective cure rate is lower look at all the studies to get a fair and balanced 4 approach and appreciation of the body of literature 4 than that. 5 5 on Secur, correct? Q. When you say 75 or less, does that mean 6 A. Correct. 6 70 to 75 would be about average? 7 7 Q. And again, we can stand by and rely on A. That would be the high end of the scale. 8 8 your reliance list for the medical literature that I mean, it all depends on which studies you have 9 9 you relied on? looked at. There are studies that show a success 10 10 MR. WALDENBERGER: Objection to the rate in the 80s. There are studies that show a 11 11 form. I believe his prior testimony was that success rate in the 50s. I would say that one of 12 some may not be on there; he just doesn't know 12 the latest meta-analysis by Tommaselli showed about 13 13 that. But with that, you can answer. a 75 percent success rate. 14 A. Again, there would be literature that I 14 Q. And so would you stand by the 75 percent 15 15 success rate as a fair estimate of the objective have reviewed that I have relied on that might not cure rate with TVT Secur? 16 16 have been on my reliance list but form this breadth 17 17 MR. WALDENBERGER: Objection to the of the opinions that I am giving. 18 I don't think that -- again, there might 18 form in that you are asking him to summarize 19 be things that are on there that I've reviewed that 19 and average out all of the complications or 20 make up the opinions that I have that might not 20 success rate for various pieces of literature that have not been identified. 21 appear in the reliance list. 21 22 Q. But you reviewed your reliance list 22 With that being stated, if you can 23 23 before you served it or before it was served, answer that question fairly and accurately, 24 correct? 24 please do so. Page 19 Page 21 1 A. Correct. 1 A. You know, I think that would be on the 2 Q. And have you had a chance to go back and 2 high end of the average success rate. 3 3 identify if there were any key studies that you Q. But you cited to a meta-analyses citing 4 4 75 objective cure for TVT Secur, correct? could think of that were not included in your 5 5 reliance list? A. Correct. б A. None that jumped out at me. 6 Q. In your opinion, is that a fair estimate 7 7 Q. And as I'm sure you can appreciate, of what the studies that that meta-analyses 8 8 Doctor, today is our opportunity to ask you about reviewed showed as a cure rate for TVT Secur? 9 your opinions and what you relied on to formulate 9 MR. WALDENBERGER: Objection to form 10 10 those opinions, so what I'm trying to avoid is, you vague. 11 11 know, before your trial testimony next week getting You can answer if you understand it. 12 a supplemental reliance list, because today is my 12 A. That would be, again, there are a number 13 13 opportunity to ask you about those studies that you of studies, the Palomba study, the Oliveira study, 14 14 relied on. that showed a 50 success rate. There are other 15 A. Yes, and I don't think you will be 15 studies that show a lower rate; Barber study, 50 to 16 getting a supplemental reliance list. 16 60 percent success rate. So, I think 75 percent 17 Q. When you performed your review of the 30 17 success rate is a high average. 18 to 50 studies on TVT Secur, what is your 18 There is the Tommaselli's older studies 19 19 understanding of the average objective cured and that have showed and 80, 85 percent success rate. 20 improved rate for TVT Secur? 20 But even in the last Cochrane analysis that was 21 MR. WALDENBERGER: Objection to form. 21 done, they showed a success rate that was lower 22 You can answer. 22 than full-length midurethral slings. 23 A. I would say that the average objective 23 Q. What is your understanding of the

6 (Pages 18 to 21)

success rate for full-length midurethral slings?

24

and subjective cure rate is lower than the

24

1 2	Page 22		Page 24
2	A. In the short term, around 90 percent	1	rate?
	success rate.	2	A. Well, again, that is a very what's
3	Q. And what is your definition of short	3	the word
4	term?	4	Q. Stringent?
5	A. In the one- to two-year studies.	5	A stringent, thank you very much,
6	Q. What about long-term?	6	criteria for measuring success. And so if you are
7	A. Well, again, it all depends on if the	7	going to use the stringent criteria, you are going
8	parameters that we are using, if you look at the	8	to have a lower success rate from any incontinence
9	urinary incontinence treatment at work, when their	9	treatment.
10	studies come out they use a composite index of	10	Q. So, if we take the urinary incontinence
11	stress test, of pad test, symptoms, and other	11	any treatment studies aside, because you referred
12	treatment for urinary incontinence.	12	to that as a cite to objective cure rates for
13	So, if you look at Richter's study, her	13	full-length slings, so if we take those studies
14	one-year success rate was around 55 percent for	14	aside, what is your appreciation
15	midurethral slings. The Barber study was about 60	15	A. You are the one that brought up those
16	percent using a composite index.	16	studies, and I was just commenting on that.
17	If you just look at cough test or if you	17	Q. Right. Well, let's back up for a
18	just look at pad test, you are going to have as	18	second. I asked you what your appreciation was for
19	your objective measure, you are going to have a	19	the average cure rate for full-length slings, and
20	higher success rate.	20	you cited to the Tomasz study.
21	Q. But, Doctor, you would agree with me	21	A. No. I was citing to Richter's 2011
22	based on the Urinary Incontinence Treatment Network	22	study and Barber's 2009 or 2010 study.
23	studies that you were citing to, using those same	23	MR. WALDENBERGER: Paul, how is this
24	objective criteria, you would admit or agree with	24	within the scope of the TVT-S report?
	Page 23		Page 25
1	me that the success rates for both the Burch	1	MR. ROSENBLATT: Because he said that
2	colposuspension and the autologous fascial sling	2	
_		2	the cure rate for Secur is lower than the
3	were significantly lower than what is typically	3	the cure rate for Secur is lower than the full-length midurethral sling, and so I'm
3 4	were significantly lower than what is typically cited as the average cure rate, correct?		
	· · · · · · · · · · · · · · · · · · ·	3	full-length midurethral sling, and so I'm
4	cited as the average cure rate, correct?	3 4	full-length midurethral sling, and so I'm trying to figure out is it 5 percent lower, 10
4 5	cited as the average cure rate, correct? MR. WALDENBERGER: Are you talking	3 4 5	full-length midurethral sling, and so I'm trying to figure out is it 5 percent lower, 10 percent lower.
4 5 6	cited as the average cure rate, correct? MR. WALDENBERGER: Are you talking about mini-slings or full-length slings?	3 4 5 6	full-length midurethral sling, and so I'm trying to figure out is it 5 percent lower, 10 percent lower. MR. WALDENBERGER: Fair enough. MR. ROSENBLATT: Now you know where I'm going, Doctor.
4 5 6 7	cited as the average cure rate, correct? MR. WALDENBERGER: Are you talking about mini-slings or full-length slings? MR. ROSENBLATT: Do you understand the question? MR. WALDENBERGER: I'm asking you	3 4 5 6 7	full-length midurethral sling, and so I'm trying to figure out is it 5 percent lower, 10 percent lower. MR. WALDENBERGER: Fair enough. MR. ROSENBLATT: Now you know where I'm going, Doctor. MR. WALDENBERGER: That was the point
4 5 6 7 8	cited as the average cure rate, correct? MR. WALDENBERGER: Are you talking about mini-slings or full-length slings? MR. ROSENBLATT: Do you understand the question? MR. WALDENBERGER: I'm asking you because that may be outside the scope of the	3 4 5 6 7 8	full-length midurethral sling, and so I'm trying to figure out is it 5 percent lower, 10 percent lower. MR. WALDENBERGER: Fair enough. MR. ROSENBLATT: Now you know where I'm going, Doctor. MR. WALDENBERGER: That was the point of my objecting, so go for it.
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7 (Pages 22 to 25)

Page 26 Page 28 1 studies that showed a much higher cure rate for TVT 1 grant or did they provide the product. Do you know 2 2 if they had any involvement in either of those 3 3 studies? A. Yes, but still there are very few 4 4 studies that showed an equivalent success rate MR. WALDENBERGER: I think he told you 5 5 he needs to see the article in order to answer 6 6 Q. But the answer to my question was yes? that question. 7 7 Q. So is your answer you don't know without A. Yes. 8 8 Q. And you would agree with me that there looking at the study? 9 9 are studies that show an objective cure rate for A. Well, I know that Dr. Hinoul, I'm not 10 TVT Secur in the 90 percentage range, correct? 10 sure whether at that point was one of the medical 11 11 directors when the TVT Secur, TVT-O study was done, A. Correct. 12 Q. And there are some studies that report 12 but either at that point or shortly thereafter 13 an even higher objective cure rate for TVT Secur, 13 became a medical director. 14 14 correct? Several of the authors both on the Hota 15 15 A. Correct. study and on the Hinoul study are key opinion 16 leaders for Ethicon. So, it's difficult to answer 16 Q. So, when you are telling me that there 17 is one study that shows it's X percent and another 17 without looking to see specifically what they 18 study showing Y percent, what I'm trying to figure 18 stated in the conflict of interest section about 19 out is how you are going about citing those 19 either their involvement with industry or the level 20 20 specific studies for your appreciation of the of industry's involvement in the study. average cure rate. 21 21 Q. Did you consider potential bias of those 22 MR. WALDENBERGER: Objection, form, 22 two studies before you stood by them to cite those 23 23 studies for the objective cure rates for TVT Secur? vague. 24 24 You can answer if you understand it. MR. WALDENBERGER: Objection to the Page 27 Page 29 A. Again, when the literature is looked at 1 form of the question, mischaracterizes them, 1 2 as in a systematic review like the Cochrane 2 but you can answer that. 3 3 analysis, the Tommaselli analysis and others, A. I looked at that for every study that I 4 4 including the FDA analysis, when you look at TVT look at. 5 Secur compared to full-length midurethral slings, 5 Q. And that would be important for you to 6 the success rate is lower and significantly lower. б have an understanding as to whether or not, for 7 7 Q. When you say significantly, that's example, a study was an investigator-initiated 8 8 statistical significance? study that had some funding provided by Ethicon, 9 9 A. Yes. correct? 10 10 Q. Now, you cited -- I'm not going to be A. Yes, and I look at that to answer your 11 11 able to list all of them, but, for example, you specific question. It would be important to have 12 cited Hota 2012, you cited Hinoul. Why did you 12 the specific article in front of me to --13 call out those specific studies when I asked you 13 Q. I'm just asking in general terms. 14 14 MR. WALDENBERGER: Let him finish his about objective cure rates? 15 A. Those were well-designed prospective 15 answer. 16 randomized control trials. 16 A. In general terms, yes, but to answer a 17 Q. And do you have any understanding as to 17 specific question, it would be important to have 18 whether or not Ethicon had any involvement in those 18 the specific article in front of me to be able to 19 19 two studies? say this is what that specific article, you know, 20 20 A. If we can pull out the studies laid out as the conflicts and what, you know, 21 21 specifically, I think there would be -- it would involvement industry had either as an 22 22 allow me to talk specifically about the answer to investigator-initiated study or a sponsor study or 23 that question, whether or not they were --23 a grant study or just key opinion leader studies. Q. And I'm not asking did they provide a 24 Q. Just speaking in general terms, you 24

Page 30 Page 32 1 wouldn't write off or discount the results of an 1 Q. Because there would just be a potential 2 RCT evaluating TVT Secur simply because there was 2 for bias, correct? 3 3 some connection, whether it was to Ethicon, whether A. Correct. 4 it was authored by a key opinion leader or a grant 4 Q. How do you distinguish between a 5 5 was provided for the study or any type of financial potential for bias and actual bias when you are 6 6 reviewing medical literature? connection, correct? 7 MR. WALDENBERGER: Objection to the 7 A. Again, you have to look at all the 8 form. I kind of lost sight of the question. 8 aspects of the study, what the hypothesis is that 9 9 Could you read that back to me, please? the study is trying to answer, what the methodology 10 10 And I'm not being critical, Paul. I was in going about answering that question, whether 11 11 iust lost it. they had stringent methodology, whether they had a 12 MR. ROSENBLATT: No worries. 12 robust enough study design to answer their 13 THE REPORTER: "Just speaking in 13 question, whether they had a significant enough 14 general terms, you wouldn't write off or 14 patient population; and then you look at what 15 15 discount the results of an RCT evaluating TVT conclusions they drew based on their analysis to 16 16 Secur simply because there was some see if the conclusions that they are drawing is 17 connection, whether it was to Ethicon, whether 17 supported by the facts that are in the study to 18 it was authored by a key opinion leader or a 18 determine if they are, you know, overselling their 19 grant was provided for the study or any type 19 conclusions based on what they found in the study; 20 of financial connection, correct?" and then I would be a little bit more concerned 20 21 MR. WALDENBERGER: Objection to form. 21 about bias. 22 22 Q. So, it would be fair to say that a You can answer. 23 23 BY THE WITNESS: potential conflict of interest is just one factor 24 A. Again, without looking at the 24 that you would look at for potential bias? Page 31 Page 33 methodology of an individual study to see if the 1 1 A. When I review the literature, whether 2 methodology was sound, to see if they had a robust 2 it's in this litigation or whether it is in my 3 3 patient population to provide a power analysis that practice in determining how I'm going to treat my 4 4 patients, yes, that is something that I take into would allow you to draw conclusions from the study, 5 5 in general the answer would be no, but we would consideration when I review any piece of 6 б have to look at the specific paper to see whether 7 7 or not bias might have influenced the study because Q. Now, Doctor, as I appreciate your 8 8 of parameters such as the ones I talked about. earlier testimony from this morning, you cited the 9 BY MR. ROSENBLATT: 9 Tommaselli study for the proposition that the 10 Q. And when you were reviewing the 30 to 50 10 average objective cure rate for TVT Secur is 75 11 11 articles on TVT Secur, did you, yourself, perform percent with the understanding that there are some 12 an analysis as to the potential bias for each of 12 studies that show a lower rate and some studies 13 13 those studies? that show a higher rate; is that accurate? 14 14 A. I think we have discussed the literature A. Correct. 15 enough in past depositions that I have looked at 15 Q. Now what I want to ask you, Doctor, is 16 all of the aspects of a study in evaluating it, and 16 taking that same approach, what is your

9 (Pages 30 to 33)

understanding of the average mesh exposure rate for

A. The Tommaselli meta-analysis showed

there was an erosion rate from their review of the

literature of 15 percent. I would say that that is

a -- from looking at the literature, that that is a

accurate representation of what was shown in the

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TVT Secur?

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that would be one of the aspects that I would look

Q. But it would be fair to say, if we are

that one factor discount the results of the study,

A. Based on that one factor, no.

study was funded by Ethicon, you would not based on

looking solely at a disclosure that indicated a

Page 34 Page 36 1 Q. Just so I'm clear, your understanding is 1 exposure rate of less than 5 percent? 2 that the average mesh exposure rate for TVT Secur 2 MR. WALDENBERGER: Objection to the 3 3 form. He is not here to guess. You can is 15 percent? 4 A. That's what Tommaselli's most recent 4 answer. 5 5 meta-analysis showed. A. The exact number I would not want to 6 б Q. But is that a number that you stand speculate on, I mean, just like I would not want to 7 behind? 7 speculate on the number that showed an erosion rate 8 8 A. That is what Dr. Tommaselli published in of over 5 percent. I mean, to look at the 9 9 his meta-analysis. There is studies that show a specific, you know, number of papers that would 10 erosion rate of 19 percent. There are other 10 give you that number, as I said, there are papers 11 11 that show an erosion rate of less than 5 percent. studies that show an erosion rate of around 10 12 percent, 8 to 9 percent. I think that between 10 12 Q. Can you cite any of them today? 13 and 15 percent would be the average erosion rate 13 A. There is a Tommaselli study. There is 14 for a TVT Secur. 14 the Anders Hamer study. So, there are studies that 15 15 show an erosion rate less than, you know, Q. You said there are some studies that 16 16 5 percent. Neuman's 2011 paper showed a lower show an erosion rate of 19 percent. How many 17 studies evaluating TVT Secur show a mesh exposure 17 erosion rate than his 2008 paper. 18 rate of 19 percent or higher? 18 Q. So, how do those lower exposure rates 19 A. The 19 percent was Hota's randomized 19 factor into your consideration when you, 20 control trial from 2012 that we talked about 20 Dr. Rosenzweig, are formulating what you believe to 21 earlier. 21 be the average mesh exposure rate for TVT Secur? 22 Q. So is the answer one study? 22 A. Again, you would look at all the papers. 23 23 A. I don't recall all of the smaller You would look at the analysis that have been done 24 studies that -- or case series that might have been 24 such as the Tommaselli systematic review to come up Page 35 Page 37 published on that. That is the highest one that I with a average that you were asking me about 1 2 saw in a randomized control trial. 2 earlier. 3 3 Q. So no others that you can think of right Q. And that average in the Tommaselli 4 now that would show a mesh exposure rate of 19 4 article that you are citing, was that specifically 5 5 percent or higher other than the Hota study? 15 percent mesh exposure for TVT Secur, or did it MR. WALDENBERGER: Objection, asked 6 also include other slings? б 7 7 and answered. You can answer it again. A. Just TVT Secur. 8 8 A. Not that I specifically recall. Q. And so that is the study that you are 9 Q. Do you know how many studies evaluating 9 standing by as far as your estimate of the mesh 10 the TVT Secur showed a mesh exposure rate of less 10 exposure rate for TVT Secur? 11 11 than 5 percent? A. That is the latest systematic review 12 A. There are studies that showed an 12 that I could find or the most contemporary 13 13 exposure rate of less than 5 percent. systematic review that I could find. 14 14 Q. My specific question, though, was, do Q. What is your understanding of the 15 you know how many studies showed a mesh exposure 15 average rate of de novo dyspareunia associated with 16 rate evaluating TVT Secur less than 5 percent? 16 the TVT Secur? 17 A. The exact number? 17 A. In the 2011 Neuman study, he quoted a 18 Q. I will take a ballpark range. 18 rate of 8 percent. The Abdelwahab paper around the 19 A. I wouldn't want to speculate on a 19 same time showed a similar dyspareunia rate. In 20 ballpark range. 20 the Anders Hamer paper they discussed pain and 21 Q. So as you are sitting here today, you 21 dyspareunia and discharge. They had a 13 percent cannot tell me or provide me your best guess as an 22 22 dyspareunia rate. So, I would say that the de novo expert offering opinions on the safety and efficacy 23 23 dyspareunia rate is probably around 8 to 10 percent of the TVT Secur how many studies show a mesh 24 for the TVT Secur. 24

Page 38 Page 40 1 Q. And what is your understanding of the --1 A. And that's why I said it's very 2 strike that. 2 difficult because -- because of the design of 3 3 You mentioned 8 to 10 percent de novo the -- you know, you have to look at the study 4 4 dyspareunia rate for TVT Secur, and what I want to design and if they actually asked those questions. 5 5 know is how far postoperatively does that include? The studies that I described actually asked those 6 6 A. Well, it's difficult to get an accurate questions. 7 7 number because, again, if the study does not Q. Again, are you aware of any studies that 8 8 describe pain and dyspareunia, we don't know show a rate of de novo dyspareunia higher than 8 to 9 9 whether that means that there was no pain or 10 percent with the TVT Secur? 10 10 dyspareunia or that the question was just not A. Sitting here today, those, that I cannot 11 11 asked. recall specifically. 12 Many of the studies include various 12 Q. So the 8 to 10 percent de novo 13 surveys, if you will, like the IIQ and the pelvic 13 dyspareunia rate for the TVT Secur is on the 14 floor symptom questionnaire or pelvic floor sexual 14 highest end of the spectrum, correct? 15 15 A. Correct. dysfunction, which includes questions on 16 16 dyspareunia but the exact number is not given. And Q. You are aware that there are clinical 17 17 studies evaluating TVT Secur that show a so while they might show that there is a change in 18 the pre-op and the post-op survey results, it's not 18 significantly lower dyspareunia rate, correct? 19 reflected in the individual parameters that are 19 A. If you have those papers, we can discuss 20 20 them in the individual. In general, there are few there. 21 So, unless a paper specifically talks 21 papers that describe dyspareunia rates that are 22 about dyspareunia, it's difficult to know whether 22 lower than that for TVT Secur. 23 23 or not the question was even answered, whether or Q. And we may look at some studies, but I'm 24 not the patient volunteered those questions. So, 24 just asking your -- just your overall impression, Page 39 Page 41 it's difficult by the study design to know what are you aware of whether or not those studies 1 2 that answer is. 2 exist? 3 3 Q. And you would agree that dyspareunia in A. And I gave you my overall impression. 4 4 Q. I don't know if I had a clean answer to general is somewhat complicated to study in 5 5 clinical studies, correct? whether or not you are aware that --6 A. It is difficult to study if the question 6 MR. WALDENBERGER: Why don't you fire 7 7 is not asked. the question again, give it another shot. 8 8 MR. ROSENBLATT: Sure. Let me reload Q. But you agree that it is difficult to 9 9 study for a number of reasons and some of those here. 10 10 BY MR. ROSENBLATT: would include whether or not you evaluate 11 11 preoperative or preexisting dyspareunia, correct? Q. You would agree that there are clinical 12 A. Well, your question was de novo 12 studies evaluating TVT Secur that show a 13 13 dyspareunia, which would mean that there was no significantly lower dyspareunia rate than 8 to 10 14 14 preexisting dyspareunia. I think a better question percent, correct? 15 would have been you have to evaluate patients who 15 MR. WALDENBERGER: Objection to form, 16 16 asked and answered. You can answer it again. are sexually active, because if they are not having

> A. There are a small number of studies that show that, yes.

Q. And one component that can make studying dyspareunia in a clinical trial difficult is determining whether or not dyspareunia was caused by a concomitant procedure as opposed to the TVT

23 Secur, correct?

24 A. If concomitant procedures were part of

11 (Pages 38 to 41)

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me?

sexual intercourse, it is very difficult to have

to be able to determine whether or not they

So, the better question is what is the

number of patients that are sexually active post-op

Q. Could you answer your own question for

pain with sexual intercourse.

developed pain, and that's --

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the study design, then there could be confounding variables from that unless the investigator was able to determine that the TVT Secur, as in the Neuman study did, was the cause of the dyspareunia.

- Q. But you would agree that it is important when evaluating de novo dyspareunia to look at other factors such as whether or not the patient underwent a concomitant procedure?
 - A. Correct.

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- Q. And some of those concomitant procedures can commonly include a vaginal hysterectomy or a surgical procedure to correct a condition called pelvic organ prolapse, correct?
- A. Those procedures cannot uncommonly be performed with a incontinence operation.
- Q. And when looking at a study that cites a dyspareunia rate, it would be important for you to have an appreciation of whether or not those patients underwent concomitant procedures, correct?
 - A. Correct.
- Q. Because concomitant procedures such as a hysterectomy or a procedure to correct pelvic organ prolapse in themselves have a risk of de novo

dyspareunia?

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that could be a compounding factor in whether or
not the patient developed postoperative
dyspareunia.

- Q. And if a patient in a clinical study underwent a TVT Secur as well as a concomitant vaginal hysterectomy, how would you do the differential diagnosis to determine whether the pain or dyspareunia was attributable to the Secur or the hysterectomy?
- A. Well, again, you would have to look at the methodology to determine how they did the pelvic organ prolapse repair.

Anterior colporrhaphies are very unlikely to cause dyspareunia. We know that from several of the studies. Posterior repairs have been associated with dyspareunia if the levator plication was done.

So, if it's characteristically described in the paper that our posterior repairs were done with levator plications, then you would rule in the posterior repair as a potential cause.

If the posterior repair is not done with a levator plication, the current studies are showing that there is a much lower rate of

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rage

A. Well, specifically the way the concomitant procedures are being done could increase the risk of dyspareunia, such as if you are doing a vaginal hysterectomy and you attach the pedicle to the vaginal cuff, that could increase your risk of dyspareunia because the pedicles are innervated, and we know from gynecology that the ovarian pedicles when pulled on or manipulated can cause a significant degree of pain. There are a lot of women that have ovarian pain specifically from an entity called ovarian torsion; and when you twist the ovarian pedicle, it can become very

We've discussed that levator plications with posterior repair significantly increases the risk of dyspareunia after a posterior compare up in the range of 20 percent compared to the newer data on posterior repairs that show only about a 4 percent or less risk of dyspareunia if no levator plication is done.

uncomfortable for a patient.

So, in order to answer that question, yes, we have to know exactly how the surgical procedures, concomitant surgical procedures were being done to be able to evaluate whether or not

Page 45

dyspareunia.

If a vaginal hysterectomy is done where the pedicles are attached to the vaginal vault, that could be a significant source of dyspareunia.

The description of what the dyspareunia is, where the location is, if palpating the sling causes pain, if you are having banding or palpability of the sling during the exam, which was described in other papers that described dyspareunia and pain associated with slings, then you could rule -- say that it is more likely that the dyspareunia is caused by the sling.

If there is no other concomitant procedure, obviously the dyspareunia would be due to the sling itself.

- Q. Now, you mentioned the anatomical location of where the pain would be with the TVT Secur. Is it your understanding that the pain or the postoperative pain and dyspareunia commonly associated with the TVT Secur would be kind of the banding underneath where the Secur sling sits?
- A. Not necessarily. We know that, you know, the pelvis isn't an isolated structure. We know that there can be some -- because of the

12 (Pages 42 to 45)

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- chronic inflammation, the chronic foreign body
 reaction, that this can impact the levator muscles,
 which are just lateral to where the TVT Secur
 fleece is supposed to lay, and that could then
 increase levator spasm and levator pain, which can
 be associated with dyspareunia.
 - Q. What is your appreciation of the rate of dyspareunia caused by TVT Secur attributable to levator spasms?
 - A. That specific description I have not seen in the studies that I've reviewed.

- Q. And so the studies that you have reviewed, where do they typically describe the pain or dyspareunia with the TVT Secur?
- A. Well, in the Neuman paper specifically, he talked about the stiffness or rigidity of the TVT Secur as causing dyspareunia. The Hota paper felt that it was sharp edges associated with the TVT Secur that would lead to pain. So,
- specifically they were describing the
 characteristic defects of the TVT Secur in those
- papers that were related to the consequence, whichwould be dyspareunia.
- Q. But that would be where the sling is, if

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- Q. So if I understand your testimony, you referred to the Neuman paper and how they theorized that the stiffness of the mesh caused dyspareunia?
 - A. Correct.
- Q. Is it your understanding that based on that theory that it would be the pain would be where the mesh is or elsewhere?
- A. I just described for you my clinical experience dealing with patients that have dyspareunia and particularly dyspareunia from midurethral slings or from single-incision slings; and they are describing the defect Dr. Neuman and Hota were describing, the defect of the sling that caused dyspareunia.

That doesn't necessarily mean that that is the only place where the patient is going to say that their pain is coming from when they are having intercourse.

- Q. Now, when you have pain or dyspareunia from a native tissue repair, do you refer to that as any type of defect causing that pain or dyspareunia?
 - A. Again, as we talked about, a levator plication with a native tissue repair would be

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I understand what you are saying?

A. Well, they were describing the characteristics of the sling that would lead to dyspareunia, and where the -- most patients when -- now we are kind of getting away from studies and clinical practice.

Most patients just know that it hurts when they are having intercourse. Some patients try to describe an anatomic location where they say most of the pain is, but most patients, if they -- so, if someone said like I have pain on introduction, many times what that is is just spasm of the muscles in anticipation of the pain with intercourse. If someone says that it's only when you hit a certain location in my vagina, then that would be a indication of where the source, if you will.

But the vast majority of patients that I see in my clinical practice say it hurts. They try to give a very vague description of where the pain is, but it's very difficult to truly say what specific anatomic location the pain is being generated by. They just know it hurts when they are having intercourse.

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an -- would be the causative factor, because what
 you are doing is you are creating a very firm shelf
 of muscle that when you are having intercourse is
 more likely to spasm or to have abnormal scarring
 in muscle that shouldn't be there.

So levator plications, we used to think that doing a levator plication would improve the anatomical results. It made the posterior repair look better but created a significant degree of dyspareunia.

- Q. And with procedures such as a hysterectomy or a pelvic organ prolapse procedure, those come with them the risk of vaginal scarring and shortening, correct?
- A. Scarring would be along the incision line because that is where the tissue is healing. Shortening would be caused by excessive removal of vaginal tissue. And another thing that has evolved is the concept that you need to take out a significant amount of vagina to create a scaffold for the prolapse.

Now, the native tissue repair is that scaffold is from bringing endopelvic fascia together and you do not take out vagina because the

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Page 50 Page 52 1 vagina is not going to act as a scaffold. 1 BY MR. ROSENBLATT: 2 Q. But the old way of doing it wasn't 2 O. Doctor, at the time TVT Secur was 3 3 necessarily outside the standard of care, correct? launched onto the market in 2006, what is your 4 MR. WALDENBERGER: Objection, outside 4 understanding of whether or not TVT Secur was 5 5 the -- hold on a second. How is that within within the standard of care for treating stress 6 б the scope of this deposition? urinary incontinence? 7 MR. ROSENBLATT: I'm just trying to 7 MR. WALDENBERGER: Objection to the 8 get his understanding as to whether or not a 8 form. You can answer. 9 9 change in the surgical procedure makes that A. Well, obviously doctors back in 2006 10 then become outside the standard of care. 10 when the TVT Secur was launched onto the market -MR. WALDENBERGER: Right. How is that 11 11 and I think we can agree that was around September 12 within the scope of a TVT-S deposition? 12 of 2006. 13 MR. ROSENBLATT: I think it is 13 Q. If that's your understanding. 14 relevant to his reasoning and understanding, 14 A. The doctors that were performing it did 15 15 not have all the information that the manufacturer and I don't think it has been previously 16 16 did about the risks associated with the device. asked. 17 MR. WALDENBERGER: It doesn't mean 17 Those risks were not communicated to doctors, as I 18 it's within the scope. I will let you go with 18 have stated in my report. All the risks that were 19 that one, but --19 associated with the device which was known to the 20 20 MR. ROSENBLATT: I mean, you can manufacturer were not communicated to doctors, and 21 object, but --21 the risks of not only the defects associated with 22 MR. WALDENBERGER: Objection is noted. 22 the device but the difficulties in doing the 23 23 I'm not going to instruct him not to answer. procedure which were not communicated to doctors 24 Go ahead. 24 were not communicated to doctors. Page 51 Page 53 1 BY THE WITNESS: 1 So, I cannot fault the doctor for having 2 A. I can't go back and say, you know, 20 2 placed the TVT Secur in 2006 because they didn't 3 3 years ago that it would be outside the standard of have all the information to make a reasonable 4 care to do the kind of repairs we used to do. 4 decision about whether or not they should be 5 5 BY MR. ROSENBLATT: placing this in a patient. 6 6 Q. And I understand all of your opinions Q. Would you agree with me that when TVT 7 7 Secur was on the market it was within the standard about the defect and the failure to warn, and we 8 8 of care for treating women with stress urinary are going to go through those in more detail, but 9 incontinence? 9 those issues aside, you would agree that TVT Secur 10 MR. WALDENBERGER: During what period? 10 was not outside the standard of care for treating 11 11 The entire time it was on the market? stress urinary incontinence? 12 MR. ROSENBLATT: I will just let 12 MR. WALDENBERGER: Objection, asked 13 13 him -- are you objecting? and answered. I will let him answer one more MR. WALDENBERGER: I am objecting 14 14 15 because I think your question is vague. 15 A. As I say, I cannot hold the doctor at 16 MR. ROSENBLATT: I will ask it 16 fault for placing a TVT Secur in 2006 because the 17 open-ended and then I will come back and 17 doctor did not have all the information that the 18 narrow it down if he needs me to. 18 manufacturer had about all the risks associated 19 MR. WALDENBERGER: Did you need that 19 with it. 20 20 narrowed down? Having known all the risks that are 21 THE WITNESS: It would be important to 21 associated with it, then it would, as it is today, 22 22 narrow it down. would be unreasonable for a doctor to place a TVT 23 MR. WALDENBERGER: I instruct you not 23 Secur. 24 to answer until he narrows it down. 24 Q. If a doctor acknowledged that he or she

14 (Pages 50 to 53)

	Page 54		Page 56
1	was aware of all of the risks, would you still	1	that there were surgeons who felt as though
2	place any fault on them for implanting a TVT Secur	2	the TVT Secur was appropriate for treating
3	while it was on the market?	3	some women with stress urinary incontinence.
4	MR. WALDENBERGER: I object to the	4	MR. WALDENBERGER: Paul, we both
5	form of the question because you are not	5	understand your question, and in my view it
6	identifying what the risks are or what the	6	not only is speculative, but aside from being
7	risks are from. So, in that regard I ask you	7	improper because it is speculative, he has
8	to rephrase the question because I don't think	8	answered it. So, I'm going to instruct him
9	it is capable of being answered as asked.	9	not to answer it because I think he has
10	MR. ROSENBLATT: I will rephrase.	10	already answered that I think three times. So
11	BY MR. ROSENBLATT:	11	if you could move on to your next question, we
12	Q. If a surgeon knew of all the risks that	12	would appreciate it.
13	you have listed in your expert report and still	13	BY MR. ROSENBLATT:
14	decided that TVT Secur was an appropriate option	14	Q. Are you unable to answer the question
15	11 1 1	15	- · · · · · · · · · · · · · · · · · · ·
	for a patient that they were treating, would you	16	because you are not sure what surgeons thought at
16	fault them for using TVT Secur?		the time?
17	MR. WALDENBERGER: Objection to the	17	MR. WALDENBERGER: I'm not permitting
18	form. You can answer.	18	him to answer it because he has already
19	A. As I say, I do not fault the doctors.	19	answered it and it is speculative, because you
20	Q. So you would agree with me that there	20	are asking him to go into the minds of other
21	are some doctors who felt like TVT Secur was an	21	people, which he can't do, but he did the best
22	appropriate option for patients with stress urinary	22	he could do by answering it the way that he
23	incontinence?	23	did, which is his answer.
24	MR. WALDENBERGER: Objection, calls	24	MR. ROSENBLATT: I think you can make
	Page 55		Page 57
1	for an explotion. Very con an exercise		
1	for speculation. You can answer.	1	your objection, and I appreciate you
2	A. As I state, I do not fault the doctors.	1 2	your objection, and I appreciate you elaborating, but I think he can still answer
	<u>^</u>		
2	A. As I state, I do not fault the doctors.	2	elaborating, but I think he can still answer the question.
2 3	A. As I state, I do not fault the doctors.Q. But my question was slightly different,	2	elaborating, but I think he can still answer the question.
2 3 4	A. As I state, I do not fault the doctors.Q. But my question was slightly different,and I appreciate your answer, but you would agree	2 3 4	elaborating, but I think he can still answer the question. MR. WALDENBERGER: Not when I tell him
2 3 4 5	A. As I state, I do not fault the doctors. Q. But my question was slightly different, and I appreciate your answer, but you would agree that when the TVT Secur was on the market there	2 3 4 5	elaborating, but I think he can still answer the question. MR. WALDENBERGER: Not when I tell him not to, which is what I'm doing, because he
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	Page 58		Page 60
1	question, so please move on to the next	1	A. Correct.
2	question.	2	Q. So, it would then be fair to say that
3	BY MR. ROSENBLATT:	3	you are not offering any case-specific opinions in
4	Q. I understand. I'm providing you the	4	the McGee case, correct?
5	previous question. Now my new question is my	5	A. Correct.
6	new question is you would agree	6	Q. And so you obviously didn't perform a
7	MR. WALDENBERGER: I'm breathless with	7	physical exam on Ms. McGee?
8	anticipation.	8	A. Correct.
9	Q that there were surgeons who felt as	9	Q. And you have never spoken to Ms. McGee?
10	though TVT Secur was an appropriate treatment	10	A. Correct.
11	option for women with stress urinary incontinence?	11	MR. WALDENBERGER: Paul, we have been
12	MR. WALDENBERGER: Paul, you have	12	going a little more than an hour, and I have
13	asked it three times.	13	drank too much water. Can we take a
14	MR. ROSENBLATT: But you haven't let	14	five-minute break for the restroom?
15	him answer all three times.	15	MR. ROSENBLATT: We can, and when you
16	MR. WALDENBERGER: Yes, I have let him	16	come back, that would be great if he could
17	answer three times, and when you try a fourth	17	answer that question.
18	and a fifth time, that's when I shut him down.	18	MR. WALDENBERGER: I'm not going to
19	He is not answering the question. He has	19	change my mind. We are going to go off the
20	answered it.	20	record.
21	MR. ROSENBLATT: But he hasn't. I'm	21	(Recess taken, 10:14 - 10:26 a.m.)
22	going to insist that he answer the question.	22	MR. LUNDQUIST: As discussed with
23	MR. WALDENBERGER: And I'm going to	23	counsel on the break, this is Will Lundquist,
24	insist that he not answer it, so why don't we	24	I'm appearing on behalf of the MDL.
	Page 59		Page 61
1	just move on to the next one.	1	Mr. Aylstock cross-noticed this deposition on
2	BY MR. ROSENBLATT:	2	behalf of the MDL as a de bene deposition.
3	Q. Are you refusing to answer the question?	3	From what I understand, to clarify, I don't
4	MR. WALDENBERGER: He is following my	4	think there is any doubt that this is a
5	instruction not to answer.	5	discovery deposition for Dr. Rosenzweig on the
6	Q. Are you refusing to answer the question?	6	TVT Secur, and I'm appearing on behalf of the
7	A. I'm following the instruction of	7	MDL at this discovery deposition for
8	counsel.	8	Dr. Rosenzweig on the Secur.
9	MR. WALDENBERGER: Right.	9	MR. ROSENBLATT: Thanks, Will.
10	Q. Doctor, did you review Ms. McGee's	10	BY MR. ROSENBLATT:
11	deposition?	11	Q. Doctor, we are just coming back from a
12	A. No.	12	break. I notice you have some binders sitting in
13	Q. Have you reviewed any depositions of	13	front of you. Do you mind telling me what those
14	Ms. McGee's family or friends?	14	are?
15	A. No.	15	A. Those are the citations that are in my
16	Q. Have you reviewed any deposition of	16	report numbered from 1 through 91.
17	Ms. McGee's treating physicians?	17	Q. And when you say citations in your
1			
18	A. No.	18	report, is that referring to either the documents
	A. No. Q. Is it fair to say that you have not	18 19	or the literature that are specifically referenced
18			
18 19	Q. Is it fair to say that you have not	19	or the literature that are specifically referenced
18 19 20	Q. Is it fair to say that you have not reviewed any deposition testimony specific to the	19 20	or the literature that are specifically referenced in the body of your report?
18 19 20 21	Q. Is it fair to say that you have not reviewed any deposition testimony specific to the McGee case?	19 20 21	or the literature that are specifically referenced in the body of your report? A. Yes, in the footnotes of the report.

16 (Pages 58 to 61)

1	Page 62		Page 64
	A. No.	1	Q. You would agree with me that TVT Secur
2	MR. ROSENBLATT: If I could, Madam	2	was a recognized treatment option for stress
3	Court Reporter, mark each of those binders as	3	urinary incontinence as early as 2006, correct?
4	Exhibit 1 and Exhibit 2.	4	MR. WALDENBERGER: What's that
5	(Rosenzweig Exhibits 1 and 2 were	5	question again?
6	marked for identification as of	6	THE WITNESS: Recognized treatment
7	2/4/16.)	7	option.
8	BY MR. ROSENBLATT:	8	MR. WALDENBERGER: I will let him
9	Q. Dr. Rosenzweig, we have just marked the	9	answer that.
10	binders that we brought with you as Exhibits 1 and	10	A. Correct.
11	2. Did you bring anything else with you?	11	MR. WALDENBERGER: Well done. I did
12	A. A copy of my report and the notice of	12	not object.
13	deposition.	13	BY MR. ROSENBLATT:
14	MR. WALDENBERGER: Just so you know,	14	Q. Doctor, you may disagree with whether or
15	Paul, we are not producing these binders.	15	not TVT Secur was an appropriate option, but you
16	They are his binders for purposes of what his	16	would acknowledge that there were some doctors who
17	materials are, but the documents are what they	17	used TVT Secur to treat stress urinary
18	are. You know what they are based on the	18	incontinence?
19	footnotes, but I just want to let you know we	19	A. There were some doctors that used TVT
20	are not giving them to you guys now. They are	20	Secur to treat stress urinary incontinence.
21	Bruce's binders.	21	Q. And as you said earlier, you don't fault
22	MR. ROSENBLATT: We are going to want	22	them for that?
23	a copy of everything.	23	A. Correct.
24	MR. WALDENBERGER: I will gladly have	24	Q. And you would agree that TVT Secur was
	Page 63		Page 65
1	agnics made for you		
т т	copies made for you.	1	an appropriate option for some patients to treat
2	MR. ROSENBLATT: Is there any	1 2	an appropriate option for some patients to treat stress urinary incontinence, correct?
2	MR. ROSENBLATT: Is there any	2	stress urinary incontinence, correct?
2	MR. ROSENBLATT: Is there any highlighting in there?	2	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the
2 3 4	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No.	2 3 4	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer.
2 3 4 5	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to	2 3 4 5	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option?
2 3 4 5 6	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that.	2 3 4 5 6	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that.
2 3 4 5 6 7	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No.	2 3 4 5 6 7	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No.
2 3 4 5 6 7 8	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break	2 3 4 5 6 7 8	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some
2 3 4 5 6 7 8	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you	2 3 4 5 6 7 8 9	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate
2 3 4 5 6 7 8 9	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem	2 3 4 5 6 7 8 9	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option?
2 3 4 5 6 7 8 9 10	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved.	2 3 4 5 6 7 8 9 10	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered
2 3 4 5 6 7 8 9 10 11	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for	2 3 4 5 6 7 8 9 10 11	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates
2 3 4 5 6 7 8 9 10 11 12 13	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it	2 3 4 5 6 7 8 9 10 11 12 13 14 15	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75
2 3 4 5 6 7 8 9 10 11 12 13 14	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared.	2 3 4 5 6 7 8 9 10 11 12 13 14	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared. BY MR. ROSENBLATT:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is your understanding of the subjective cure rate for
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared. BY MR. ROSENBLATT: Q. Is there any reason you didn't bring all	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is your understanding of the subjective cure rate for TVT Secur?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared. BY MR. ROSENBLATT: Q. Is there any reason you didn't bring all of the literature that's on your reliance list?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is your understanding of the subjective cure rate for TVT Secur? A. It is less than the 75 percent.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared. BY MR. ROSENBLATT: Q. Is there any reason you didn't bring all of the literature that's on your reliance list? A. It would be quite a voluminous task.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is your understanding of the subjective cure rate for TVT Secur? A. It is less than the 75 percent. Q. How much less?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared. BY MR. ROSENBLATT: Q. Is there any reason you didn't bring all of the literature that's on your reliance list? A. It would be quite a voluminous task. Q. Doctor, I want to go back to something.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is your understanding of the subjective cure rate for TVT Secur? A. It is less than the 75 percent. Q. How much less? A. Again, I would say in the range of a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared. BY MR. ROSENBLATT: Q. Is there any reason you didn't bring all of the literature that's on your reliance list? A. It would be quite a voluminous task. Q. Doctor, I want to go back to something. I'm going to try to phrase it to avoid your counsel	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is your understanding of the subjective cure rate for TVT Secur? A. It is less than the 75 percent. Q. How much less? A. Again, I would say in the range of a high end would be 70 percent.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. ROSENBLATT: Is there any highlighting in there? THE WITNESS: No. MR. WALDENBERGER: You would have to answer that. THE WITNESS: No. MR. ROSENBLATT: During the next break I just want to flip through it, and if you could give me a flash drive then, problem solved. MR. WALDENBERGER: Even better, yes, we will do that, and I will get that in the works for you right now. We won't have it for you today, but I will get it to you when it gets prepared. BY MR. ROSENBLATT: Q. Is there any reason you didn't bring all of the literature that's on your reliance list? A. It would be quite a voluminous task. Q. Doctor, I want to go back to something.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	stress urinary incontinence, correct? MR. WALDENBERGER: Objection to the form. You can answer. A. Do I feel it was an appropriate option? Q. We will start with that. A. No. Q. But you would agree that there were some doctors who did feel that it was an appropriate option? A. You asked that question. I answered that question yes. Q. I also want to go back to something. When we were talking about the objective cure rates for TVT Secur, I believe you gave me the figure 75 percent based on the Tommaselli study. What is your understanding of the subjective cure rate for TVT Secur? A. It is less than the 75 percent. Q. How much less? A. Again, I would say in the range of a

17 (Pages 62 to 65)

Page 66 Page 68 1 systematic reviews. 1 Q. That would also include a simple 2 Q. And you would acknowledge that there are 2 take-down procedure? 3 3 studies evaluating TVT Secur that report a much A. You mean a release procedure? 4 higher subjective cure rate than 70 percent, 4 Q. Yes. 5 5 correct? A. Yes. 6 6 A. Correct. Q. For a release procedure you are 7 Q. How do those studies factor into your 7 essentially just pulling the mesh down with maybe a 8 8 analysis of 70 percent? nerve hook and cutting the mesh so you are not 9 9 A. I reviewed again all the studies that cutting into the urethra, correct? 10 10 look at more favorable results. There are also A. If that's possible. Sometimes we have 11 studies that show that there was a 30 to 50 percent 11 to transect it in situ without the ability to get 12 subjective cure rate. 12 an instrument such as a nerve hook or a hemostat or 13 Q. Now, when you said you reviewed all the 13 a Lahey or a very narrow right angle behind it, but 14 studies, I just want to make something clear. You 14 because of the degree of scarification, scar plate 15 15 are referring to the studies listed in your formation, the degree of fibrosis, chronic foreign 16 16 reliance list, correct? body reaction, to be able to safely separate it so 17 MR. WALDENBERGER: Objection, form, 17 that we would just separate it in situ. 18 asked and answered. I don't believe he said 18 Q. One of the benefits with at least the 19 that, but he can answer that question and 19 TVT mesh is that it's blue, correct? 20 20 explain it again. A. That was one of the things that was 21 A. Again, I reviewed a number of studies on 21 cited back in 2004, if I remember correctly, when 22 TVT Secur. All of them may or may not be on my 22 it was converted from a clear to a blue color. It 23 reliance list. 23 would help with implantation but would also help 24 Q. But if they were important, you would 24 with removal. Page 67 Page 69 1 Q. Did you find that to be beneficial when 1 put them on your reliance list? 2 MR. WALDENBERGER: Objection, asked 2 you were removing? 3 3 and answered. Paul, I thought we had gone A. Sometimes it's difficult to tell whether 4 4 over this, but I'm happy to have him answer it the blue is from a vein or a blood vessel or the 5 5 again. Go for it. blue is from the mesh. I have, unfortunately, 6 A. There might be some important studies 6 transected a number of blood vessels thinking that 7 7 that might not have made it on to my reliance list. it was the mesh only to find out that it was a 8 8 Q. Now, Doctor, I know you have testified blood vessel. So, sometimes it made it easier, 9 9 sometimes it increased the degree of complications to some of this in the past, so I'm going to try to 10 10 breeze through this portion very quickly, and where of the procedure. 11 11 I'm trying to get is very specific to TVT Secur, Q. I believe you told us of those 200 12 but just to set up my questions, I do want to ask 12 removal or excision, or I use the word take-down --13 13 you some that you have already answered. what did you use? 14 14 A. Release. I believe you told us you have removed 15 or explanted approximately 200 slings? 15 Q. I will start over. 16 A. Correct. 16 So, of those 200 removal, excision or 17 Q. And when we say removed or excise, I 17 release procedures that you performed on slings, I 18 believe you testified or you told us that would 18 believe you told us about 40 to 50 of those 19 include trying to remove as much of the mesh as 19 procedures would have been Ethicon's TVT meshes? 20 20 A. That would be a rough estimate. It is possible? 2.1 21 probably a little bit higher now since I have done A. Correct. 22 a few more since the last discussion where I gave a 22 Q. That would also include a trimming a 23 small mesh exposure? 23 number like that. 24 24 Q. How many TVT meshes have you removed in A. Correct.

18 (Pages 66 to 69)

Page 70 Page 72 1 2016? 1 retropubic quickly goes up, you know, towards the 2 A. Two or three. I think I just did one 2 urogenital diaphragm underneath the urethra. The 3 3 obturators go lateral out to the obturator foramen, last week. 4 4 Q. So that number may be 40 to 53 now, so it's easy to tell a retropubic from a obturator 5 5 approximately? foramen. 6 6 A. Yes. Whether or not it is a mini-sling, you 7 Q. And of those, I will say, 40 to 53 7 can feel that, particularly with the Secur, because 8 8 Ethicon meshes that you have removed or excised or there is no anchor into the obturator muscle or the 9 9 released, how many of those were laser-cut TVT obturator foramen. The sling ends at the obturator 10 10 slings? foramen or, excuse me, the obturator internus 11 11 A. That I can't tell you because I don't muscle. 12 always get the product, a UPIN number I think is 12 MR. ROSENBLATT: I want to go ahead 13 what it's called, or identification number; and 13 and mark as Exhibit 3 what's been marked as 14 even when I have looked on the product 14 the notice of deposition. 15 15 (Rosenzweig Exhibit 3 was marked for identification sticker, I haven't seen where it 16 16 specifically states whether it's mechanical cut or identification as of 2/4/16.) 17 17 BY MR. ROSENBLATT: laser cut. Q. Am I correct that you brought a copy of 18 Q. But you know if there is an "L," that 18 means it is laser cut, on the product sticker, 19 19 this notice with you? 20 20 right? A. Yes, I did. 21 A. Yes. 21 Q. And it says -- strike that. 22 Q. How many of those 40 to 53 Ethicon TVT 22 If you could turn with me to Page 3 slings that you have removed were TVT Secur? under document request. 23 23 24 A. Less than five, and those I would know 24 A. Yes. Page 71 Page 73 1 Q. I'm looking at number 4. It says a copy 1 were laser cut. 2 Q. And how would you know that the TVT 2 of your complete file in this case. Did you bring 3 3 a copy of your complete file in this case? Securs were laser cut? 4 A. Because all the TVT Securs are laser 4 A. No. From my understanding, that's going 5 5 to be made available to you electronically. cut. 6 Q. And when you are excising or removing or MR. ROSENBLATT: Counsel, you can б 7 7 releasing one of the Ethicon TVT meshes, how are verify that. 8 8 you able to determine whether it is a TVT Secur, a MR. WALDENBERGER: Are you defining 9 TVT retropubic or a TVT obturator sling? 9 case as the McGee case or are you defining 10 A. From the operative report. 10 case as -- how are you defining case? I guess 11 11 Q. So, as I understand it, if you have the that's the interesting way of answering your 12 operative report you are able to determine whether 12 question, because if it is the McGee case, he 13 it's retropubic, obturator or a mini-sling? 13 doesn't have any McGee documents. 14 14 A. Correct. MR. ROSENBLATT: The complete case 15 Q. Sometimes you have the product code? 15 file for TVT Secur. 16 A. Correct. And sometimes, as I have had a 16 MR. WALDENBERGER: Yeah, sure. 17 few are Exact, and then I would know that it is a 17 MR. ROSENBLATT: Okay. Counsel, you 18 laser-cut mesh because all Exacts are laser cut. 18 will make that available electronically? 19 19 Q. And without having the benefit of the MR. WALDENBERGER: Yes. 20 operative report or the product code, how are you 20 MR. ROSENBLATT: I would ask if there 21 able to determine whether a TVT mesh is TVT 21 are any highlighted documents that we have the 22 22 retropubic, TVT obturator or TVT Secur? benefit of the highlighted documents whether 23 A. Well, it's very -- it's relatively easy 23 you want to scan those in or however you want 24 to tell a retropubic from a obturator, because the 24 to do that.

19 (Pages 70 to 73)

	Page 74		Page 76
1	MR. WALDENBERGER: To the extent any	1	question, and then I'm just going to put an
2	exist, sure. I don't know whether any do or	2	objection on the record, but you can answer
3	not.	3	that.
4	BY MR. ROSENBLATT:	4	A. No.
5	Q. Doctor, when you review the literature	5	MR. WALDENBERGER: And Paul, as you
6	do you manually highlight your literature?	6	know, when you e-mailed me, I objected to this
7	A. There are times that I do, there are	7	particular request because it was outside the
8	times that I don't.	8	scope of this particular deposition, which is
9	Q. Do you recall whether or not you	9	why he doesn't have any of those materials
10	highlighted any TVT Secur literature?	10	here.
11	A. In this case?	11	MR. ROSENBLATT: And I will just put
12	Q. We are here talking about TVT Secur.	12	on the record as well that my understanding is
13	I'm wondering if you have highlighted any TVT Secur	13	in the Carlino case Judge Powell said we could
14	medical literature that would assist you in	14	cite to him as precedent that he is requiring
15	supporting your opinions?	15	experts to produce all of their invoices.
16	A. In this case?	16	So, I'm just renewing my request for
17	MR. WALDENBERGER: Are you talking	17	those documents, and we can revisit that
18	ever, has he ever done it?	18	issue, but your objection is noted, and we
19	MR. ROSENBLATT: In any TVT Secur	19	would like to continue pursuing those
20	•	20	documents.
	case.	21	
21	A. Yes, I might have.		MR. WALDENBERGER: Sure.
22	Q. And would you be able to make those	22 23	BY MR. ROSENBLATT:
23	highlighted articles available to your counsel to		Q. But Doctor, you do have a copy of all of
24	provide to us?	24	your invoices that you could provide to your
	Page 75		Page 77
1	A. I can try to do that.	1	counsel?
1 2	A. I can try to do that.Q. And would you have highlighted any TVT	1 2	counsel? A. For this case?
	A. I can try to do that.Q. And would you have highlighted any TVTSecur company documents to support your opinions in		counsel? A. For this case? Q. For your work in all the pelvic mesh
2	A. I can try to do that. Q. And would you have highlighted any TVT Secur company documents to support your opinions in any TVT Secur case?	2	counsel? A. For this case? Q. For your work in all the pelvic mesh litigation.
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20 (Pages 74 to 77)

	Page 78		Page 80
1	for your opinions in any TVT Secur case?	1	that we received a few days ago. Did you ask your
2	A. In any TVT Secur case? I don't I	2	attorney to include any additional studies or
3	don't even have an estimate.	3	documents that are now included in this list?
4	Q. How many hours did you spend preparing	4	A. I did not.
5	for this deposition?	5	MR. WALDENBERGER: Just so you know,
6	A. Approximately 22 hours.	6	Paul, we prepared this list.
7	Q. And you said you have not submitted a	7	MR. ROSENBLATT: Okay.
8	bill for that?	8	MR. WALDENBERGER: And the stuff on
9	A. Correct.	9	the end, there is a KM Bates stamp. That's
10	Q. And for those 22 hours, how much of that	10	because when we looked at the list we maybe
11	would be meeting with your attorney?	11	saw that those weren't included before. That
12	A. Approximately seven hours.	12	may be duplicative, but we re-Bates-stamped
13	Q. And of those seven hours, was that all	13	with a "KM" in an abundance of caution. There
14	in one day?	14	may be things that were on the other list, but
15	A. Correct.	15	it is so big that we would just like to err on
16	Q. And when was that?	16	the side of caution.
17	A. Yesterday.	17	MR. ROSENBLATT: I appreciate that.
18	Q. And who did you meet with?	18	BY MR. ROSENBLATT:
19	A. The two gentlemen sitting here.	19	Q. Doctor, just speaking in general terms,
20	Q. And so the other 15 hours, was that	20	if there was a device that could positively affect
21	spent working on your expert report?	21	incontinence issues for women, would that be a good
22	A. Correct.	22	thing?
23	Q. Doctor, let me go ahead and mark this	23	A. Hypothetically?
24	while it is in front of me. I'm marking as Exhibit	24	Q. Yes.
	D [[0]		
	Page 79		Page 81
1		1	
1 2	4, this is the supplemental expert report that you submitted in this case?	1 2	A. Hypothetically, yes.
	4, this is the supplemental expert report that you		A. Hypothetically, yes.Q. And would you say ideally or
2	4, this is the supplemental expert report that you submitted in this case? A. Correct.	2	A. Hypothetically, yes.
2 3	4, this is the supplemental expert report that you submitted in this case?	2	A. Hypothetically, yes. Q. And would you say ideally or hypothetically you would agree that less invasive
2 3 4	4, this is the supplemental expert report that you submitted in this case? A. Correct. (Rosenzweig Exhibit 4 was marked for	2 3 4	A. Hypothetically, yes. Q. And would you say ideally or hypothetically you would agree that less invasive is better than more invasive? A. That statement I can't answer because
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21 (Pages 78 to 81)

Page 82 Page 84 1 surgical, an invasive surgical procedure. 1 A. If they are a keloid former, which means 2 Q. And Doctor, I think I said I was 2 that they have an exaggerated scar, they would be 3 3 speaking in general terms, but speaking in general concerned about that, yes. 4 terms related to treatment for stress urinary 4 Q. And there may be some women who may be a 5 5 incontinence. model or they are just overly concerned about their 6 6 A. And again, with the same qualifiers, appearance and wouldn't want any type of scar, 7 without more information it would be very difficult 7 correct? 8 to answer that question. 8 A. That is a possibility, yes. 9 9 Q. And you would agree that in general no Q. And so you agree it is potentially a 10 exit wounds is better than exit wounds? 10 benefit to have a procedure that could treat 11 11 incontinence that would not leave a cosmetic scar? A. Again, in that are we talking about 12 gunshots or --12 MR. WALDENBERGER: Objection to form 13 MR. WALDENBERGER: Or are we talking 13 You can answer. 14 about stress urinary incontinence treatment? 14 A. Again, without knowing anything more A. Because if you have a 15 than just that hypothetical, I can't answer that 15 16 16 through-and-through gunshot wound, that's probably question. 17 more preferable than no exit wound because then the 17 Q. And generally speaking, would you agree 18 bullet is bouncing around in someone's body. 18 that less anesthesia is better than more 19 MR. WALDENBERGER: I think he is going 19 20 20 to rephrase his question. A. And we are talking about general 21 Q. Doctor, I have got a list of questions 21 anesthesia or we are talking about regional 22 here, and they are all related to incontinence 22 anesthesia or we are talking about local 23 23 surgery in general. anesthesia? 24 A. Okay. 24 Q. Let's talk about local versus general Page 83 Page 85 Q. Is that enough of a qualifier there? for a stress urinary incontinence procedure. 1 1 2 A. Excellent. 2 A. Local anesthesia would be beneficial 3 3 Q. So, with that understanding, would you compared to general anesthesia. 4 agree that no exit wounds is potentially better 4 Q. And you would agree that a quicker 5 5 than exit wounds? operation would be better than a longer operation? 6 A. And we are talking about what length of 6 A. Not necessarily. 7 7 Q. And why is that? operation. Whether it's the difference between 15 8 8 A. Again, without more information about minutes and 20 minutes wouldn't make a significant 9 9 what is taking place with the exit wounds, it would difference. The difference between 20 minutes and 10 be very difficult to answer that even in a general 10 four hours would make a significant difference. 11 11 hypothetical sense. Q. And when you say it could make a 12 Q. And again, generally speaking about SUI 12 difference, what is the reason behind that 13 13 surgeries, you would agree that it's a benefit to statement that there could be a big difference 14 be able to accommodate patients who are concerned 14 between the operative times? 15 with any type of cosmetic scarring? 15 A. Between 20 minutes and four hours? 16 MR. WALDENBERGER: Objection to the 16 Q. Yes. 17 form, vague. You can answer if you understand 17 A. The operation that's longer than two 18 18 hours would increase the risk of deep venous 19 19 A. Again, without anything more than just thrombosis, postoperative pneumonia and 20 20 cosmetic scarring, I can't answer that question. postoperative infection. 2.1 21 Q. Have you ever had any patients come to Q. In your opinion, is there a significant 22 you who were concerned about scars that they may 22 difference between a 10-minute procedure and a 23 have on their abdomen or pubic area from an 23 one-hour procedure? 24 24 incontinence surgery? A. Potentially.

22 (Pages 82 to 85)

	Page 86		Page 88
1	Q. And what would that difference be?	1	form, vague. You can answer it if you
2	A. Well, usually within an hour you are	2	understand it.
3	going to have only a minimal risk of increasing the	3	A. Again, I don't understand your question.
4	intraoperative morbidity from a procedure, so there	4	I
5	probably is not a significant difference in the	5	MR. WALDENBERGER: That's fine. He
6	timeframe that you gave me.	6	doesn't understand your question.
7	Q. And that brings up another point. It	7	Q. You agree it would be a benefit if a
8	would be beneficial to reduce intraoperative	8	woman was able to drive herself to and from an
9	complications, if possible?	9	operation the same day, correct?
10	A. Yes.	10	A. After surgical procedures our
11	Q. And if it was possible to make an	11	recommendation is that the patient would not drive
12	operation quicker without introducing new risks,	12	themself home from the operation even if it is done
13	that would be beneficial?	13	under local anesthesia.
14	A. Again, not necessarily.	14	Q. But you would agree that that would be a
15	Q. You would agree that it would be	15	benefit, correct?
16	beneficial to be able to treat a patient with	16	A. I would not recommend any patient drive
17	general stress urinary incontinence as well as ISD	17	themself home after a surgical procedure even if it
18	or intrinsic sphincter deficiency, correct?	18	is done under local anesthesia.
19	MR. WALDENBERGER: Could you read that	19	Q. Would you agree that it's a benefit to
20	question back.	20	have a patient leave the procedure that same day
21	THE REPORTER: "You would agree that	21	and go home as opposed to staying overnight in a
22	it would be beneficial to be able to treat a	22	hospital?
23	patient with general stress urinary	23	A. There is an economic benefit of a
24	incontinence as well as ISD or intrinsic	24	same-day surgery versus an overnight stay.
	Page 87		Page 89
1	sphincter deficiency, correct?"	1	However, if you admit the patient as a 24-hour
2			
	MR. WALDENBERGER: I object to the	2	
3	MR. WALDENBERGER: I object to the form of the question.	2	observation, that economic benefit is minimized and
3 4	form of the question.	3	observation, that economic benefit is minimized and there doesn't appear to be a significant difference
4	form of the question. A. Well, intrinsic sphincter deficiency is	3 4	observation, that economic benefit is minimized and there doesn't appear to be a significant difference between a observation versus a outpatient
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4 5 6 7 8	form of the question. A. Well, intrinsic sphincter deficiency is a form of stress urinary incontinence. Q. Have you seen studies that would indicate that a retropubic approach is better at resolving ISD than other approaches?	3 4 5 6	observation, that economic benefit is minimized and there doesn't appear to be a significant difference between a observation versus a outpatient procedure. Q. Would you agree that it would be a
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	form of the question. A. Well, intrinsic sphincter deficiency is a form of stress urinary incontinence. Q. Have you seen studies that would indicate that a retropubic approach is better at resolving ISD than other approaches? A. That has been suggested in the literature. Q. And so you would agree that there would be some benefit to be able to perform either a retropubic procedure or an obturator procedure, depending on the type of incontinence a patient had? A. I don't understand your question. Q. You would agree that I will re-ask it. You would agree that it would be a benefit to have a versatile procedure that would	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	observation, that economic benefit is minimized and there doesn't appear to be a significant difference between a observation versus a outpatient procedure. Q. Would you agree that it would be a benefit for a patient to undergo a procedure where she did not have to go home with a catheter? A. Yes. Q. You agree that it would be beneficial for a woman to undergo a procedure that would allow her to return to her normal activities quicker? A. What normal activities are you talking about? Q. Just generally speaking, walking, running, lifting, going back to work. A. Going back to work would be an economic benefit. I'm not sure that walking most patients after any surgical procedure are encouraged to get up and walk as quickly after the surgical procedure as possible.

23 (Pages 86 to 89)

Page 92 Page 90 1 MR. ROSENBLATT: Yeah. 1 Q. And that would be true for both the 2 MR. WALDENBERGER: How do you define 2 short term and the long term? 3 3 your own normal activities? A. Yes. 4 BY MR. ROSENBLATT: 4 Q. You would agree that less mesh is better 5 5 Q. When you are talking about a patient, than more mesh? 6 б how do you define normal activities? A. Mesh cannot create the chronic foreign 7 A. So how do I counsel my patients about 7 body reaction, chronic inflammatory response, the 8 8 what -- when they can go back to work, when they degradation and contraction if it is not in a 9 9 can have sexual intercourse, when they can exercise location. Now, the exact tissue response is the 10 10 or when I expect them to get out of bed and walk same at the -- where the mesh is. 11 around? Because I expect my patient to get out of 11 Q. I appreciate that, Doctor. I'm not 12 bed and walk around as soon after the surgical 12 clear on your answer, so I'm hoping I can ask it 13 procedure as possible. 13 again and maybe better understand your answer. 14 Q. So, you would agree it would be a 14 Yes or no: Would you agree that in 15 15 benefit for a patient to be able to have sex sooner general less mesh is better than no -- than more 16 16 after a procedure than later? mesh? 17 MR. WALDENBERGER: Objection to the 17 MR. WALDENBERGER: Objection, asked 18 form, vague. I think it is relative to time, 18 and answered, and you do not have to limit 19 but you can answer if you understand that. 19 your answer to yes or no. Please answer the 20 THE WITNESS: It would be beneficial 20 question as you see fit as long as it is 21 to have intercourse sooner? 21 responsive to his question. 22 MR. WALDENBERGER: Do you understand 22 A. Mesh cannot create the chronic 23 23 the question? inflammation, chronic foreign body reaction, 24 THE WITNESS: No. 24 contraction, degradation and the effect on the Page 91 Page 93 BY MR. ROSENBLATT: tissue that it has if it is not in that location. 1 2 Q. Do you agree it would be beneficial for 2 but the effect on the tissue is the same where the 3 3 a patient to undergo a procedure that would allow mesh is. 4 her to return to work faster than another 4 Q. But you would agree it would be 5 5 procedure? beneficial to have less mesh because that would A. Return to work? then mean that there is less of a reaction? 6 6 7 7 Q. Yes. A. There is not less of a reaction. There 8 8 is less of an area where that reaction is taking A. As an economic benefit, yes. 9 9 Q. And you would certainly agree that if place. 10 10 Q. So, in your opinion is there any benefit there was a single mother who was the breadwinner, 11 11 that that could be an important factor for that to 8 centimeters worth of mesh as opposed to 40 or 12 patient in considering her surgical options, 12 45 centimeters worth of mesh? 13 13 correct? A. Well, we know that not all 45 14 14 MR. WALDENBERGER: I don't even know centimeters of mesh is in the body at the end of 15 what to say. Objection, you can answer. 15 the surgical procedure. So, where the mesh is not 16 A. Well, most of my patients would fall 16 is not going to undergo a chronic foreign body 17 under the economic umbrella that their surgical 17 reaction, chronic foreign body, mesh contraction, 18 procedure is covered by their short-term 18 mesh degradation, mesh deformation and the 19 19 consequences of that, which is erosion, pain, disability, and so I don't see that that would be 20 20 dyspareunia, chronic pain, the need for chronic that significant unless they did not have that 21 21 revision procedures; all the things that are ability to be covered under short-term disability. 22 22 Q. You agree that less postoperative pain illustrated in my report. 23 is better than more postoperative pain? 23 Q. Would you say that less mesh leads to 24 24 fewer complications as opposed to more mesh leading

24 (Pages 90 to 93)

	Page 94		Page 96
1	to more complications?	1	there will not be a foreign body response.
2	A. The mesh cannot create a complication	2	Q. So is that a yes or a no?
3	where it isn't.	3	A. In the area where there is no mesh,
4	Q. Doctor, what I'm trying to get from you	4	there will be no foreign body response.
5	is whether or not you as a surgeon would see any	5	Q. Doctor, are you unable to answer the
6	benefit to treating a patient's condition with less	6	question with a "yes" or a "no"?
7	mesh, less surface area, than more mesh, whether	7	MR. WALDENBERGER: He has answered the
8	it's 8 centimeters versus 15 centimeters?	8	question, Paul, but you can ask it again.
9	MR. WALDENBERGER: Is that a question?	9	Q. I said, are you unable to answer the
10	That sounded like a statement rather than a	10	question with a "yes" or a "no"?
11		11	A. The answer is that if there where
12	question.	12	
	MR. ROSENBLATT: I added a statement	13	there is no mesh, there will be no foreign body
13	at the end.		response.
14	MR. WALDENBERGER: So I don't know	14	Q. And my followup to that is, wouldn't you
15	what the question, so let's start there.	15	agree that that is a benefit to have less area
16	MR. ROSENBLATT: I will strike that.	16	where you would have a foreign body reaction?
17	BY MR. ROSENBLATT:	17	MR. WALDENBERGER: Objection, asked
18	Q. My question is, Doctor, do you see a	18	and answered. You can answer it again.
19	benefit as a surgeon to implanting less mesh in a	19	A. You will not have the consequence of the
20	patient to treat stress urinary incontinence than	20	foreign body reaction where the mesh is not.
21	implanting more mesh, or do you see no benefit?	21	Q. Doctor, would you agree that less mesh
22	MR. WALDENBERGER: Objection to the	22	means less inflammation and less mesh left behind?
23	form, asked and answered several times. You	23	MR. WALDENBERGER: Objection,
24	can answer again.	24	compound. You are asking about inflammation.
	Page 95		Page 97
			rage 77
1	A. I don't see any benefit to implanting	1	MR. ROSENBLATT: I will break it down
1 2	A. I don't see any benefit to implanting mesh.	1 2	
			MR. ROSENBLATT: I will break it down
2	mesh. Q. And I understand that's your opinion.	2	MR. ROSENBLATT: I will break it down for your counsel.
2 3	mesh. Q. And I understand that's your opinion. What I'm trying to pin down, Doctor, is whether or	2	MR. ROSENBLATT: I will break it down for your counsel. MR. WALDENBERGER: And for him, but
2 3 4	mesh. Q. And I understand that's your opinion. What I'm trying to pin down, Doctor, is whether or not there is a benefit to using less mesh or	2 3 4	MR. ROSENBLATT: I will break it down for your counsel. MR. WALDENBERGER: And for him, but thank you. BY MR. ROSENBLATT:
2 3 4 5	mesh. Q. And I understand that's your opinion. What I'm trying to pin down, Doctor, is whether or not there is a benefit to using less mesh or whether it doesn't matter if you use more mesh	2 3 4 5	MR. ROSENBLATT: I will break it down for your counsel. MR. WALDENBERGER: And for him, but thank you. BY MR. ROSENBLATT: Q. Do you need me to separate those two?
2 3 4 5 6	mesh. Q. And I understand that's your opinion. What I'm trying to pin down, Doctor, is whether or not there is a benefit to using less mesh or whether it doesn't matter if you use more mesh because you are going to have the same reaction?	2 3 4 5 6 7	MR. ROSENBLATT: I will break it down for your counsel. MR. WALDENBERGER: And for him, but thank you. BY MR. ROSENBLATT: Q. Do you need me to separate those two? A. Yes, please.
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25 (Pages 94 to 97)

Page 98 Page 100 MR. WALDENBERGER: What number is 1 A. If the mesh cannot create the chronic 1 2 inflammation, the chronic foreign body reaction, 2 this? Five, six. 3 3 scar plate formation where the mesh is not. MR. ROSENBLATT: I have just handed 4 Q. Doctor, would you agree that less mesh 4 you what we have marked as Exhibit 6. 5 5 left behind is a benefit compared to more mesh left (Rosenzweig Exhibit 6 was marked for 6 6 identification as of 2/4/16.) behind? 7 7 BY MR. ROSENBLATT: A. More mesh left behind will be more areas 8 8 where the mesh is creating chronic foreign body Q. And just hang on to that for a second, 9 9 reaction, chronic inflammation, chronic Doctor, but first I have a question. 10 scar-plating and irritating more nerves than an 10 Is a smaller area of chronic foreign 11 11 area where there is less mesh. body reaction a better result than a larger area? 12 Q. And now that we have established that, 12 A. The foreign body response will be the 13 would you agree that that would be a benefit to 13 same in the smaller area. It's just that it is 14 have less of a foreign body reaction? 14 where the mesh is not you would have -- you would 15 15 A. The foreign body reaction where the mesh not have a chronic foreign body reaction. 16 16 is is going to be the same. If there is no mesh in Q. And you agree that that would be a 17 another location, there will not be a foreign body 17 benefit? 18 reaction where the mesh is not. 18 A. For the area where there is no chronic 19 Q. And you would agree that that would be a 19 foreign body reaction, yes. 20 20 Q. So are you saying that there is no benefit? 21 A. No, because of the area where the mesh 21 difference if the mesh is present? 22 is you are getting chronic foreign body reaction, 22 A. You cannot have a chronic foreign body 23 chronic inflammation, scar plating, nerves being 23 reaction, degradation, contraction where the mesh 24 injured and all of the responses or all of the 24 is not. Page 99 Page 101 complications that I highlight in my report. 1 Q. Doctor, if you have pain in your big toe 2 Q. Doctor, have you ever issued the opinion 2 and you have a headache -- strike that. 3 3 that the TVT Abbrevo is safer than the TVT-O? I have handed you what's been marked as 4 MR. WALDENBERGER: Objection. How is 4 Exhibit 6. Do you recognize this document? 5 5 that within the scope of this deposition? A. Yes. 6 MR. ROSENBLATT: It is within the 6 Q. And please tell us what this document 7 7 scope of the deposition because I'm talking is. 8 about sling length here and he has not 8 A. This is a fourth supplemental report in 9 answered my question, so... 9 the Huskey, et al., case in the West Virginia MDL. 10 MR. WALDENBERGER: He has answered the 10 Q. And you recall that the Huskey case was 11 11 question just fine. a TVT-O laser-cut case? 12 MR. ROSENBLATT: I'm making a 12 A. Correct. 13 13 comparison here. Q. And in this supplemental report I believe you stated that Ethicon had a safer option MR. WALDENBERGER: I will let him 14 14 15 answer the question. 15 for patients other than the TVT-O in the Abbrevo sling, is that correct? 16 A. The Abbrevo is 12 centimeters. It goes 16 17 through the obturator internus, the obturator 17 A. Correct. 18 foramen, the obturator externus muscle. 18 Q. And I understand it's your opinion that 19 19 no mesh should be used in the pelvic floor, There is no mesh that is in the 20 obturator -- or excuse me -- the adductor longus, 20 correct? 21 the adductor brevis; and therefore, there would not 21 A. Correct. 22 be that irritation of those muscles, there would Q. And you stand by that statement today? 22 23 not be the irritation of the obturator nerve from 23 A. Correct. 24 24 the Abbrevo. And you also said in your report that

Page 102 Page 104 1 answer the question wouldn't that be a benefit 1 the Abbrevo sling has less mesh than the TVT-O, 2 which means less foreign body response, less 2 if there is less mesh even though you have the 3 3 inflammation and less mesh left in the adductor same reaction in that area. 4 muscle, resulting in less chronic pain, chronic 4 MR. WALDENBERGER: He has answered all 5 5 groin pain and chronic pelvic pain for the patient, of those questions inside and outside the 6 6 context of both the TVT-S and his fourth correct? 7 7 A. Correct. supplemental report. 8 8 Q. And you still stand by that today? So, I'm really not clear where you are 9 9 A. As I was saying, you cannot get a going with this, but I will let it go on for a 10 10 few more questions, but I really do think it chronic foreign body response, chronic inflammation in the adductor muscles because there would be no 11 11 is outside the scope of the TVT-S. So, if you 12 mesh in the adductor muscles. 12 could ask a question, take it from there. 13 13 BY MR. ROSENBLATT: Q. And part of your opinion that support --14 or strike that. 14 Q. Doctor, which product would you say is 15 safer: The TVT Abbrevo or the TVT-O laser cut? 15 So, your opinion in the Huskey case was 16 16 MR. WALDENBERGER: Objection. Don't that the TVT Abbrevo laser-cut, 12-centimeter mesh 17 was a safer option than the longer TVT-O laser-cut 17 answer. Outside the scope of this deposition. 18 mesh? 18 Q. Are you going to answer? 19 A. For Ms. Huskey, yes. 19 MR. WALDENBERGER: I'm instructing him 20 20 Q. And what specific to Ms. Huskey would not to. 21 21 differentiate your opinion from, say, another Q. Doctor, which product is safer: The TVT 22 patient? 22 Abbrevo or the TVT Secur? 23 23 MR. WALDENBERGER: Objection to the A. Well, she was having pain from 24 irritation of her obturator nerve and the chronic 24 form. You can answer. Page 103 Page 105 foreign body reaction and chronic inflammation of 1 1 A. Between the two, I don't think that one 2 the tape left in the adductor muscles lying next to 2 is safer. 3 3 the obturator nerve was leading to her chronic Q. Doctor, between TVT Secur and TVT-O 4 4 laser cut, which product is safer? obturator nerve pain and her chronic leg pain. 5 5 Q. So you can't make a general statement MR. WALDENBERGER: Objection to the 6 that TVT Abbrevo is safer than TVT-O laser cut? 6 form. You can answer. 7 A. The effect of the Abbrevo with the 7 A. The TVT Secur, there would be no mesh 8 8 left in the adductor muscles, resulting in less chronic foreign body reaction, chronic 9 9 inflammation, degradation, contraction in the chronic leg pain, chronic groin pain, chronic 10 10 vagina is going to be the same. pelvic pain. 11 11 Q. I don't think you are answering my Q. And I take it you would see that as a 12 question here, so I'm going to keep trying until 12 benefit over the TVT-O? 13 13 you do. Is it true that you cannot make a general A. There would be less mesh left in the 14 14 statement that the TVT Abbrevo is a safer option adductor muscles, so there would be no chronic 15 than the TVT-O laser-cut mesh? 15 foreign body response, no inflammatory response in 16 MR. WALDENBERGER: Paul, why is this 16 the adductor muscles. There would be minimal 17 inside the scope of a TVT-S deposition? 17 chance of irritating the obturator nerve. 18 MR. ROSENBLATT: I'm making a 18 Q. And you would agree that that would be a 19 19 comparison to his previous opinion about how a benefit? 20 20 shorter mesh is safer than a longer mesh when MR. WALDENBERGER: Objection to the 21 2.1 they are both laser cut, and here we are form. Paul, your use of the terms like "safe" 22 22 talking about a even shorter mesh and all he and "benefit" over and over and over again, 23 23 is saying is, well, you are going to have a implying that he has an opinion that these 24 24 reaction if there is mesh there and won't things are safe or have some type of benefit.

27 (Pages 102 to 105)

Page 106 Page 108 1 And I know that he has given it in terms of a 1 the question. Move on, Paul. 2 comparison, but you keep asking him that way 2 BY MR. ROSENBLATT: 3 3 and --Q. But you can't answer it -- and I'm fine 4 BY MR. ROSENBLATT: 4 with moving on, but you can't answer that with a 5 5 Q. Well, let me put a little caveat in yes or no, can you? 6 6 here. With the understanding that you think no MR. WALDENBERGER: He answered the 7 mesh should be used for stress urinary incontinence 7 question. He actually described what he was 8 repair, with that understanding, can we work with 8 talking about, so he answered the question. 9 9 that? MR. ROSENBLATT: Without answering the 10 10 A. Yes. question. 11 11 MR. WALDENBERGER: He answered the Q. With that understanding, would you agree 12 that less mesh is better than more mesh if you had 12 question just fine. He has answered the 13 to use mesh? 13 question. Move on to the next one. 14 MR. WALDENBERGER: Paul, we have gone 14 BY MR. ROSENBLATT: 15 over the less mesh and more mesh thing. 15 Q. Doctor, between -- strike that. 16 16 MR. ROSENBLATT: If he answers my We are still talking about the same 17 question, I could move on. 17 caveat here, that you do not think any mesh used 18 MR. WALDENBERGER: He has told you 18 for stress urinary incontinence is a safe option, 19 time and time again when you have more mesh, 19 correct? 20 you have more foreign body reaction. You have 20 A. Correct. 21 less mesh, you don't have the reaction with 21 Q. With that understanding, between TVT 22 the --22 Secur and TVT retropubic mechanically cut, in your MR. ROSENBLATT: He hasn't said that, 23 23 expert opinion is one safer than the other? 24 he hasn't said that. 24 MR. WALDENBERGER: Objection to form Page 107 Page 109 BY THE WITNESS: 1 1 asked and answered. You can answer. 2 A. Where the mesh is not, there is no 2 A. Mechanical cut mesh leads to roping, 3 3 foreign body reaction, there is no inflammation, fraying, curling, which leads to a certain set of 4 4 complications. TVT Secur is a heavyweight, small there is no scar plating, there is no degradation 5 5 there is no contraction. pore, laser-cut, short mesh, which is stiffer, 6 6 BY MR. ROSENBLATT: which leads to a certain set of complications. 7 7 Q. Right. And a smaller area where you are Q. And what are you relying on for that 8 having that same reaction would be better than a 8 statement that a stiffer mesh leads to more 9 9 larger area where you are having that same complications? 10 10 reaction? A. The Liang paper, the Moalli papers, the 11 11 MR. WALDENBERGER: Objection, asked Bosse papers showing that stiffer mesh increases 12 and answered. 12 cell death, which will increase erosions; leads to 13 13 A. As I state in my report, there would be vaginal thinning; leads to smooth muscle damage, 14 14 no inflammation, no mesh left behind in the which will lead to stress urinary incontinence; 15 adductor muscles with a shorter mesh. 15 leads to poor collagen functioning, which will lead 16 16 Q. So, I'm going to try to make this very to -- also, their latest study shows that you have 17 simple. Do you or do you not see any benefit to 17 an induction of bad macrophages, which will lead to 18 having a shorter mesh? 18 more of a chronic inflammatory response, more scar 19 19 A. A shorter mesh means that there is no plating -- I will slow down a little bit -- more 20 20 mesh left behind in the adductor muscles outside muscles being -- excuse me -- more nerves being 21 21 the obturator externus muscle; therefore, there irritated; therefore, more erosions, more pain, 22 would be less leg pain, groin pain for the patient. 22 more dyspareunia and all of the other risks that 23 Q. So you can't answer that question? 23 I've cited in my report. MR. WALDENBERGER: He just answered 24 24 Q. Would the TVT -- strike that.

28 (Pages 106 to 109)

Page 110 Page 112 1 In your opinion, would the TVT Secur be 1 A. A lighter weight, larger pore mesh would 2 a safer mesh if it was mechanically cut instead of 2 be the safer mesh. 3 3 Q. So you can't answer the question if we laser cut? 4 MR. WALDENBERGER: Objection to the 4 only increase the pore size but the weight stays 5 5 form. You can answer. the same? 6 6 A. A larger pore, lighter weight mesh would A. No. A safer, a safer --7 7 MR. ROSENBLATT: You see how he be safe. 8 answered that with a "yes" or a "no"? That 8 Q. Doctor, you cannot answer the question 9 9 was incredible. only focusing on the pore size, correct? 10 A. A safer mesh would be a larger pore, 10 A. A lighter weight, larger pore mesh would 11 lighter weight mesh that was laser cut. 11 be safe. 12 MR. ROSENBLATT: Can you read that 12 Q. So is the answer you can't answer that 13 13 answer back for me. auestion? 14 THE REPORTER: "No. A safer, a 14 MR. WALDENBERGER: The answer is 15 15 that's what his answer is. Again, your use of safer --16 16 the term "safe," even if you put this caveat "Mr. Rosenblatt: You see how he 17 answered that with a 'yes' or a 'no'? That 17 on it, which is fine, but your use of the term 18 was incredible. 18 "safe" has certain implications. And I 19 "Answer: A safer mesh would be a 19 understand why you are doing it. It's because 20 larger pore, lighter weight mesh that was you can have a transcript, you can cut that 20 21 laser cut." 21 particular part out, you can cross-examine 22 BY MR. WALDENBERGER: 22 that he used the word "safe" when he answers 23 Q. Doctor, would you agree that there is a 23 with the word "safe." But he is giving this 24 benefit to mesh being cut with a laser? 24 answer to this question. Page 111 Page 113 1 A. A larger pore, lighter weight mesh or 1 MR. ROSENBLATT: He is giving opinions 2 for less mesh left behind on the cutting room 2 about whether something is safer or not, and 3 3 he is saying that Ultrapro is safer than TVT floor? 4 4 Secur, so I'm --Q. Can you not answer the question the way 5 5 I phrased it? MR. WALDENBERGER: And that's A. I'm wondering what benefit you mean. 6 6 consistent with what he just testified right 7 7 Q. Okay. I want to play a little game. We now. 8 8 are going to change one component, and I want to MR. ROSENBLATT: Right. 9 see how that affects your answer, and the three 9 MR. WALDENBERGER: Correct. So we are 10 components we are dealing with are the pore size, 10 in agreement. 11 MR. ROSENBLATT: Please limit your 11 the weight, how the mesh is cut. 12 A. Okay. 12 objection to form and let me handle this here. 13 13 MR. WALDENBERGER: I will object and Q. And we are still operating under the 14 assumption that no mesh in your opinion is the best 14 interject as I see fit, so let's continue. 15 15 MR. CAMPBELL: We have been at it for mesh. 16 16 more than an hour since the last break, so I'm A. Yes. 17 Q. If you only increase the pore size of 17 happy to have just a 10-minute break. 18 TVT Secur and left everything else the same, would 18 MR. WALDENBERGER: Sure. 19 that make it safer? 19 (Recess taken, 11:26 - 11:45 a.m.) 20 A. A larger pore, lighter weight mesh would 20 (Rosenzweig Exhibits 7 through 13 21 21 were marked for identification as be the safer mesh. Q. But you didn't understand my question. 22 of 2/4/16.) 22 23 We are keeping the weight the same. We are only 23 BY MR. ROSENBLATT: 24 24 Q. All right, Doctor. We are back from a making the pore size bigger.

29 (Pages 110 to 113)

Page 114 Page 116 quick break here. If you could pull out in front 1 1 E-t-h-i-s-o-r-b, fleece end does not allow for 2 of you Exhibit 4, which is your expert report. 2 fixation to adequately allow, quote-unquote, tissue 3 3 integration, therefore increasing the chances of A. Yes. 4 4 Q. At the top it says that all of your recurrence of stress urinary incontinence. 5 opinions are held to a reasonable degree of medical 5 The size of the introducer is large for 6 б certainty. What does that mean? the description of the incision size, which 7 A. Reasonable degree of medical certainty? 7 therefore leads to a dragging of either 8 8 Q. Yes. periurethral or perivaginal tissue, which leads to 9 9 A. That the probability is greater than 51 tissue disruption and also tissue damage which will 10 10 lead to pain and dyspareunia. percent. 11 Q. And you see here the summary of 11 The depth of the incision needs to be 12 opinions, it lists "A" through letter "N"? 12 deeper so that the mesh will lay flat and be able 13 A. Yes. 13 to be introduced in a way that decreases tissue 14 Q. Is that a fair representation of your 14 disruption and tissue irritation and the mesh to 15 opinions regarding the TVT Secur in this case? 15 lay flat to decrease complications. 16 A. Correct. 16 The IFU does not adequately describe the 17 Q. And this would be in addition to your 17 way to -- the incision, the depth of the incision, 18 opinions listed in your general report? 18 and how to properly, quote-unquote, tension the 19 19 mesh, which needs to be placed, quote-unquote, with 20 20 Q. But my understanding is these opinions more tension than the standard TVT or TVT-O. 21 are specific to the TVT Secur? 21 There needs to be, quote-unquote, 22 A. Yes. 22 pillowing of periurethral tissue between the pores Q. If you could, just tell me what your 23 23 at the time of insertion in order to be able to get 24 expert opinions are in this case. 24 the mesh in the appropriate location to treat Page 115 Page 117 1 1 stress urinary incontinence. MR. WALDENBERGER: Relating to the 2 Secur, you mean? 2 The TVT Secur is a more difficult sling 3 MR. ROSENBLATT: Yes. 3 to insert, therefore needs a increased level of 4 4 A. As I stated in my report, I go over what skill than the average surgeon in order to get a 5 5 are the defects in not only the design but the adequate success rate and to minimize 6 warnings of the TVT Secur and the harms that are 6 complications. 7 7 associated with those defects. That is a brief summary of all the 8 8 Q. And what are your opinions about the opinions that are further stated in more detail in 9 design defects? 9 my report. 10 10 Q. But it's fair to say that your opinions A. That the laser cutting of a small mesh, 11 11 which is heavyweight, small pore, of a 6-mil fiber that you plan to offer are contained within this 12 size leads to rigidity and stiffness. I think we 12 supplemental report? 13 have also discussed degradation, contraction, 13 A. Correct. 14 14 chronic foreign body reaction. Q. What are all of the complications that 15 That the introducer is of a design that 15 you believe come about due to the design of TVT 16 increases the risk of injury, the introducer being 16 Secur? 17 the arrow shape of the introducer, and that the 17 A. As I've described in my report, the list 18 introducer has a difficulty of getting into the 18 of complications include erosion, pain, urinary 19 right position and into the right location and 19 problems, erosion that can decrease the quality of 20 removal; that upon dislodging the introducer you 20 life, dyspareunia, need for additional surgery, 2.1 21 can or removing the introducer you can dislodge the need for removal surgery, urinary tract infections, 22 22 sling, which will decrease its ability to lead to dysuria, de novo urgency, mesh exposure, fistula

30 (Pages 114 to 117)

formation, hematomas, abscess formation, narrowing

of the vaginal walls, erosion that can occur at any

23

24

23

24

stress urinary incontinence.

The Ethisorb fleece end, Ethisorb,

	Page 118		Page 120
1	time during the patient's life, mesh contracture	1	Q. And what are those?
2	causing pain, complications that make it impossible	2	A. Erosion, bleeding and dyspareunia.
3	to have sexual intercourse beside the others that	3	Q. Any others?
4	I've described that are associated with the	4	A. Failure and the need to reoperate for
5	polypropylene mesh in general.	5	recurrent stress urinary incontinence or treatment
6	Q. Are there any unique complications	6	for recurrent stress urinary incontinence.
7	related to the TVT Secur that would not occur with	7	Q. Are you aware of any studies showing no
8	any of the other Ethicon TVT products?	8	statistical significance between the rate of
9	A. Are you talking about the performance of	9	erosions when comparing TVT Secur to any of the
10	the Secur, the surgical procedure versus the	10	other TVT products?
11	surgical procedure or complications in general?	11	A. Am I aware that there are studies that
12	Q. Right now I'm focused on complications.	12	show there are no differences?
13	MR. WALDENBERGER: Meaning the injury		Q. Yes.
14	to the person?	14	A. Yes.
15	MR. ROSENBLATT: Yes.	15	Q. How many studies are you aware of that
16	MR. WALDENBERGER: Do you understand	16	show no difference?
17	it that way?	17	A. The exact number I do not recall off
18	THE WITNESS: No.	18	the sitting here today.
19	BY MR. ROSENBLATT:	19	Q. Can you recall any?
20	Q. Okay. So, when we say complications,	20	MR. WALDENBERGER: Meaning the title?
21	what are you referring to?	21	MR. ROSENBLATT: Yes, author, year.
22	A. Well, I mean, there can be complications	22	A. The Anders Hamer study did not show a
23	meaning adverse events to the patient and there can	23	difference between vaginal erosions, if I recall,
24	be complications meaning difficulty with the	24	but did show a much higher rate of urethral
21	· · · · · · · · · · · · · · · · · · ·		
	Page 119		
-		_	Page 121
1	surgical procedure.	1	erosions.
2	surgical procedure. Q. Okay. I'm focused just on the patient.	2	erosions. Q. Any others?
2	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the	2	erosions. Q. Any others? A. The Tommaselli study, I mean, there are
2 3 4	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can	2 3 4	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar
2 3 4 5	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with	2 3 4 5	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate.
2 3 4 5 6	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products?	2 3 4 5 6	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about
2 3 4 5 6 7	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the	2 3 4 5 6 7	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing
2 3 4 5 6 7 8	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur	2 3 4 5 6 7 8	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that
2 3 4 5 6 7 8	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was	2 3 4 5 6 7 8	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to
2 3 4 5 6 7 8 9	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market.	2 3 4 5 6 7 8 9	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding?
2 3 4 5 6 7 8 9 10	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market. Q. And I think you answered a different	2 3 4 5 6 7 8 9 10	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding? A. Many studies did not talk about bleeding
2 3 4 5 6 7 8 9 10 11	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market. Q. And I think you answered a different question. You said that those complications were	2 3 4 5 6 7 8 9 10 11	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding? A. Many studies did not talk about bleeding specifically.
2 3 4 5 6 7 8 9 10 11 12 13	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market. Q. And I think you answered a different question. You said that those complications were known. I'm asking what, if any, are the unique	2 3 4 5 6 7 8 9 10 11 12	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding? A. Many studies did not talk about bleeding specifically. Q. But are you aware of any that did talk
2 3 4 5 6 7 8 9 10 11 12 13 14	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market. Q. And I think you answered a different question. You said that those complications were known. I'm asking what, if any, are the unique complications that a patient might experience with	2 3 4 5 6 7 8 9 10 11 12 13 14	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding? A. Many studies did not talk about bleeding specifically. Q. But are you aware of any that did talk about it that determined that there was no
2 3 4 5 6 7 8 9 10 11 12 13 14 15	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market. Q. And I think you answered a different question. You said that those complications were known. I'm asking what, if any, are the unique complications that a patient might experience with a TVT Secur that she would not experience with any	2 3 4 5 6 7 8 9 10 11 12 13 14 15	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding? A. Many studies did not talk about bleeding specifically. Q. But are you aware of any that did talk about it that determined that there was no statistical significance?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market. Q. And I think you answered a different question. You said that those complications were known. I'm asking what, if any, are the unique complications that a patient might experience with a TVT Secur that she would not experience with any other Ethicon TVT product, or your answer could be	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding? A. Many studies did not talk about bleeding specifically. Q. But are you aware of any that did talk about it that determined that there was no statistical significance? A. Yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market. Q. And I think you answered a different question. You said that those complications were known. I'm asking what, if any, are the unique complications that a patient might experience with a TVT Secur that she would not experience with any other Ethicon TVT product, or your answer could be all the complications are the same. A. I would say all the complications are the same. Q. Okay. Are there any complications that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding? A. Many studies did not talk about bleeding specifically. Q. But are you aware of any that did talk about it that determined that there was no statistical significance? A. Yes. Q. Are you able to name any of those studies right now? A. It's not described in the Hota study, the Masta the Masata study and several other
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	surgical procedure. Q. Okay. I'm focused just on the patient. So, in terms of complications that can occur to the patient, what are the unique complications that can occur with TVT Secur that are not associated with any of the other TVT products? A. As I described in my report, all the complications that are associated with TVT Secur were known prior to the time that the Secur was placed in the market. Q. And I think you answered a different question. You said that those complications were known. I'm asking what, if any, are the unique complications that a patient might experience with a TVT Secur that she would not experience with any other Ethicon TVT product, or your answer could be all the complications are the same. A. I would say all the complications are the same. Q. Okay. Are there any complications that could occur to the patient that you believe happen	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	erosions. Q. Any others? A. The Tommaselli study, I mean, there are studies that have shown that there was a similar erosion rate. Q. I will ask the same question about bleeding. Are you aware of any studies comparing TVT Secur to any of the other TVT products that showed no statistical significance with respect to bleeding? A. Many studies did not talk about bleeding specifically. Q. But are you aware of any that did talk about it that determined that there was no statistical significance? A. Yes. Q. Are you able to name any of those studies right now? A. It's not described in the Hota study, the Masta the Masata study and several other studies.

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1 significance with respect to dyspareunia? 2 A. Yes. 3 Q. And can you list those studies for me? 4 A. There are a number of studies, the exact 5 names. There is the Tommaselli studies that didn't 6 show any difference between dyspareunia; Barber 7 study that didn't show any difference in 8 dyspareunia, just to name a couple. 9 Q. And how do those studies affect your 10 opinion as far as TVT Secur causing more erosions, 11 bleeding and dyspareunia? 1 no difference in failure rate between TVT Secur any other TVT mesh? 2 any other TVT mesh? 3 A. We have already discussed that. That would be the opposite of the success rate. We have already discussed that the first and success rate and success rate. We have already discussed that the first and success rate and success rate. We have already discussed that that would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the success rate. We have already discussed that. That would be the opposite of the
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11bleeding and dyspareunia?11reoperation rates?12A. Than the other slings that we are12A. If it doesn't fail, you wouldn't need to13talking about, right?13do a reoperation.
12 A. Than the other slings that we are 12 A. If it doesn't fail, you wouldn't need to 13 talking about, right? 13 do a reoperation.
13 talking about, right? 13 do a reoperation.
Q. No. I'm asking let me back up here. 14 Q. Have you seen any studies that showed in
15 You previously told me that TVT Secur experiences 15 statistical difference in reoperation rates between
16 more erosions, bleeding and dyspareunia. Is it 16 TVT Secur and any other TVT mesh?
17 your opinion that there is a statistically 17 A. Specifically looking at reoperation
significant increased risk of erosion, bleeding and la rates, I don't specifically recall those studies,
dyspareunia with TVT Secur as opposed to the other 19 but if you look at failure rates and then failure
20 TVT products? 20 necessitating a reoperation, then there are studies
21 A. The Cochrane analysis that was done in 21 that show a similar failure rate.
22 2014 showed that there was a adverse event profile 22 Q. And if you turn to Page 5 of your
23 noted significantly worse and higher rate of 23 report, looking at the big paragraph there
24 operative blood loss, mesh erosion and bladder and 24 MR. WALDENBERGER: Let me catch
Page 123 Page
1 urethral erosion. 1 with you, hold on.
2 Q. Other than the Cochrane review, what 2 MR. ROSENBLATT: Sure. Startin
3 else are you relying on? 3 "It was unreasonable on Ethicon's part to
4 A. The Cochrane review, which is a 4 expect surgeons"
5 systematic review. 5 MR. WALDENBERGER: Yes.
6 Q. Anything else? 6 BY MR. ROSENBLATT:
7 A. My review of the literature. 7 Q. All of the complications that you list
8 Q. How much more likely is a patient to 8 there, is it correct that you believe all of thos
9 experience a mesh erosion with a TVT Secur as 9 complications should have been in the TVT secur as
10 opposed to any of the other TVT products? 10 IFU?
MR. WALDENBERGER: Objection to the 11 A. Contraction, degradation, chronic pa
12 form. You can answer. 12 dyspareunia, unable to treat pain, injury to the
13 A. As I've stated, that there is a probably 13 partner in sexual intercourse, vaginal narrow
14 10 to 15 percent risk. According to Tommaselli's 14 vaginal scarring, fibrosis, scar plate formatio
15 systematic review, there was a 15 percent risk of 15 deformation, yes.
16 erosion from TVT Secur, which would be 16 Q. Hypothetically, if all of those were
approximately three times higher than the risk for 17 listed in the IFU, would you then think that the
18 the other TVT products. 18 IFU was adequate and sufficient?
19 Q. So doing basic math, it's my 19 A. In respect to warnings?
20 understanding that you would consider the other TVT 20 Q. Yes.
21 products to have about a 5 percent mesh exposure 21 A. If all the warnings that I described in
22 rate? 22 my report that were not in the IFU, then I wo
, J. P. C.
23 A. 4 to 5 percent, yes. 23 find and if it talked about frequency, sever

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Page 126 Page 128 1 the complications, then yes. 1 a rule of thumb for contraction, I would agree with 2 Q. So if I were to copy and paste this 2 that. It has been described as being higher, up to 3 3 paragraph that you have here and put it in the IFU, 50 percent, but Dr. Arnaud says the rule of thumb 4 that would still be inadequate in your opinion? 4 is 30 percent contraction. 5 5 A. It would need to describe frequency, Q. What level of evidence would you 6 6 severity, treatability, permanency and a consider Dr. Arnaud's rule of thumb? 7 7 A. What level of evidence? He is a medical description of treatment, all of the things that 8 8 I've described in my report that the warnings are director at Ethicon, and he has information about 9 9 the literature, about the performance of his 10 Q. And are you able to provide me with the 10 products, so I would say that someone who is a 11 frequency percentage for each of these 11 medical director should have a very high level of 12 complications listed here that are specifically 12 evidence. 13 related to TVT Secur? 13 Q. And what is your understanding of the 14 A. There are some that I can recall from 14 literature of the frequent receive mesh shrinkage 15 15 and contraction with TVT Secur? the literature. I would say that the manufacturer 16 16 is the one that would know about the complications A. From the literature? 17 of their product and, therefore, should be able to 17 Q. Yes. 18 supply doctors with the frequency, with the 18 A. I have not seen a description of mesh, 19 severity, with the treatability and the permanency 19 that a randomized control trial has looked at, TVT 20 of the device. 20 Secur at the time of placement and then following 21 Q. Let's walk through each one of these 21 it up with ultrasound over time to show the level 22 briefly, and you just let me know if you can tell 22 of contraction. 23 me what the frequency is that you believe should be 23 Q. What is the frequency based on the 24 in the IFU, and then we will move on to the next 24 medical literature of degradation with TVT Secur? Page 127 Page 129 one. So, we will start with mesh shrinkage and 1 A. All mesh degrades. 1 2 contraction. Do you have a specific frequency for 2 Q. To what extent does the TVT Secur 3 mesh shrinkage and contraction that occurs with TVT 3 degrade? 4 4 Secur? A. Well, it depends on the time of 5 5 A. Yes, all mesh slings and contracts. degradation. According to PA Consulting that Q. I'm asking about specifically about TVT 6 issued a report after reviewing the literature to 6 7 7 Secur. Ethicon, they state that all mesh degrades and 8 8 A. All mesh including the TVT Secur shrinks degradation starts at implantation. 9 9 Q. And your opinion isn't limited to TVT and contracts. 10 Q. What percentage? 10 Secur, but that would be all mesh? 11 11 A. All mesh shrinks and contracts. A. Correct. 12 Q. By how much is what I'm asking for, the 12 Q. What is the frequency based on the 13 medical literature that you would attach to chronic 13 frequency. 14 14 A. Well, I will use Dr. Arnaud's rule of pelvic pain for TVT Secur? 15 thumb. That has been described as a 30 percent 15 A. The Anders Hamer paper showed 13 percent 16 contraction rate. It has been described as even 16 chronic pelvic pain or pain associated with the TVT 17 higher than that, up to a 50 percent contraction 17 Secur. 18 rate. 18 Q. Is that the highest percent you have 19 Q. And you as a pelvic floor surgeon would 19 seen for chronic pelvic pain? 20 want to rely on Dr. Arnaud's statement? 20 A. In the meta-analysis by -- and I'm 21 21 blocking the name right now -- Muretti -- no. A. Dr. Arnaud is one of the medical 22 22 directors of Ethicon, has significant information Masati -- we've discussed it at the other

33 (Pages 126 to 129)

depositions -- shows that it is as high as 15

23

24

23

24

about the performance of the product; and if he

feels that a 30 percent contraction rate is a -- is

1 Q. In TVT Secur? 2 A. In midurethral slings. 3 Q. We are just talking about TVT Secur. 4 A. I would add TVT Secur in that, Masati. 5 Q. So when you are describing the frequency 6 that should be in the IFU, you think the highest 1 described in the literature, but that 2 information that the manufacturer 3 Q. What about narrowing? 4 A. Same answer. 5 Q. Shortening? 6 A. Same answer.	
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4 A. I would add TVT Secur in that, Masati. 4 A. Same answer. 5 Q. So when you are describing the frequency 5 Q. Shortening?	
5 Q. So when you are describing the frequency 5 Q. Shortening?	
The should be in the free voicining the inglication of the A. Maine answer.	
7 purported frequency in the medical literature 7 Q. Fibrosis?	
8 should be the number that's attached to the 8 A. Same answer.	
9 complication? 9 Q. Scar plate formation?	
10 A. I think that would be very important for 10 A. All mesh causes scar plate	formation.
11 doctors to be able to tell their patients what the 11 Q. Deformation?	
12 worst-case scenario would be. 12 A. Deformation, that is inform	nation that
13 Q. And so these figures that you are 13 the manufacturer should have.	
14 providing for me, would it be fair to say that they 14 Q. The safety and effectivene	ss of the TVT
15 are worst-case scenario? 15 Secur has not been evaluated in eit	
16 A. There are some. There are some that 16 clinical studies or randomized con-	_
17 would be averages. 17 A. Long-term, yes.	
18 Q. Okay. So we will move to dyspareunia. 18 Q. And you describe long-term	m as
19 What is the frequency percentage that you would 19 A. Five to ten years.	
20 attach to dyspareunia for TVT Secur? 20 Q. Are you aware of any five-	-vear studies
21 A. We have already discussed that. 21 evaluating the TVT Secur?	,
22 Q. You said 8 to 10 percent? 22 A. I think there was one Tom	maselli study
23 A. Correct. 23 that was a five-year study.	
Q. What about for untreatable and permanent 24 Q. Are you aware of any othe	ers?
Page 131	Page 133
1 pain? 1 A. I think there was one or two or	thers.
2 A. If you look at the literature for 2 Q. So does that statement still sta	
3 patients that have been treated for pain, the 3 A. Those were not randomized c	
4 untreatability for pain is anywhere from 20 to 40 4 trials, if I remember correctly.	
5 percent, so patients 5 Q. So, your testimony is that you	are not
6 Q. For the TVT Secur? 6 aware of any randomized controlled to	
7 A. For midurethral slings. 7 followup that goes out to five years?	
8 Q. Okay. I'm just talking about TVT Secur. 8 A. Not that I specifically recall.	
9 A. And I would add TVT Secur into that. 9 Q. But if you were aware of such	a study.
10 Q. So 20 to 40 percent? 10 that would be an important study to ac	-
11 A. Of patients that have chronic pain, the 11 reliance list, correct?	J
12 inability and the permanency of the treatment. 12 A. Yes.	
13 Q. What is the frequency that you would 13 Q. The necessity of multiple surg	geries to
14 attach to partner penile injury with intercourse 14 remove mesh; what is the frequency of	
15 related to the TVT Secur? 15 for TVT Secur?	
16 A. I don't know if there is a number that 16 A. That would be based on the co	omplications
has been placed in the literature. That should be 17 of pain, erosion, dyspareunia. So, if y	_
18 a number that the manufacturer should have from 18 the treatment algorithm, approximatel	
19 complaints that they have been given. 19 of erosions are going to require surgice	-
Q. Have you reviewed those documents? 20 management. I would say that would	
21 A. No, I have not. 21 ballpark for the other complications o	
22 Q. And what is the percentage of vaginal 22 dyspareunia.	
22 Q. And what is the percentage of vaginal 22 dyspareunia. 23 scarring that you would attach to the TVT Secur? 23 Q. I'm going to jump back to son	nething. I

34 (Pages 130 to 133)

1	Page 134		Page 136
	MR. WALDENBERGER: I didn't like the	1	behind.
2	sound of that, Paul, I'm just going to tell	2	BY MR. ROSENBLATT:
3	you. We were doing well for such a long time.	3	Q. Okay. Do you recognize what I have
4	Don't make me regret it. Go for it.	4	handed you as Exhibit 7?
5	BY MR. ROSENBLATT:	5	A. Yes.
6	Q. Do you agree that it would be preferable	6	Q. This would be the Neuman paper that you
7	to have less mesh instead of more mesh?	7	cited for the proposition that TVT Secur causes
8	A. Preferable	8	more dyspareunia than TVT-O?
9	MR. WALDENBERGER: Hold on a second.	9	A. Yes.
10	Object to the form, asked and answered. The	10	Q. You would agree with me TVT Secur caused
11	only thing different is you are using the word	11	significantly lower vaginal and thigh pain than
12	"preferable" as opposed to "safer" or "more	12	TVT-O, correct?
13	beneficial." With that being said, I will	13	A. Yes.
14	allow him to answer the question yet one more	14	Q. And you would agree that it would be
15	time. Go for it.	15	preferable to have less postoperative vaginal and
16	A. Preferable for the areas where the mesh	16	thigh pain?
17	is not.	17	MR. WALDENBERGER: Objection to the
18	Q. And if you had to choose,	18	form. You can answer.
19	hypothetically, with all things remaining equal,	19	A. Based on the results of this study.
20	and we are talking complications, efficacy, will	20	Q. Yes?
21	you agree that it would be preferable to have a	21	A. Based on the results of this study.
22	sling with less mesh as opposed to more mesh?	22	Q. And you find this study to be
23	MR. WALDENBERGER: Objection, asked	23	reliable
24	and answered. You can answer again.	24	A. Yes.
Page 135			Page 137
1	A. Preferable for where the sling is not.	1	Q and authoritative?
2	Q. I now want to turn to Page 16 of the	2	. **
			A. Yes.
3	report and towards the bottom of the first	3	A. Yes.Q. And this is the type of study that
3 4	report and towards the bottom of the first paragraph you say, "In 2011, Dr. Neuman published	3 4	
	· 1		Q. And this is the type of study that
4	paragraph you say, "In 2011, Dr. Neuman published	4	Q. And this is the type of study that surgeons in your field would review on a regular
4 5	paragraph you say, "In 2011, Dr. Neuman published his findings that the TVT caused significantly more	4 5	Q. And this is the type of study that surgeons in your field would review on a regular basis?
4 5 6	paragraph you say, "In 2011, Dr. Neuman published his findings that the TVT caused significantly more dyspareunia than the TVT-O due to the	4 5 6	Q. And this is the type of study that surgeons in your field would review on a regular basis?A. Yes.
4 5 6 7	paragraph you say, "In 2011, Dr. Neuman published his findings that the TVT caused significantly more dyspareunia than the TVT-O due to the stiffness/rigidity of the mesh."	4 5 6 7	 Q. And this is the type of study that surgeons in your field would review on a regular basis? A. Yes. Q. Is this the type of information that you
4 5 6 7 8	paragraph you say, "In 2011, Dr. Neuman published his findings that the TVT caused significantly more dyspareunia than the TVT-O due to the stiffness/rigidity of the mesh." Did I read that correctly?	4 5 6 7 8	 Q. And this is the type of study that surgeons in your field would review on a regular basis? A. Yes. Q. Is this the type of information that you would use to help counsel patients about either the
4 5 6 7 8 9	paragraph you say, "In 2011, Dr. Neuman published his findings that the TVT caused significantly more dyspareunia than the TVT-O due to the stiffness/rigidity of the mesh." Did I read that correctly? A. Correct.	4 5 6 7 8 9	 Q. And this is the type of study that surgeons in your field would review on a regular basis? A. Yes. Q. Is this the type of information that you would use to help counsel patients about either the TVT-O or the TVT Secur?
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	paragraph you say, "In 2011, Dr. Neuman published his findings that the TVT caused significantly more dyspareunia than the TVT-O due to the stiffness/rigidity of the mesh." Did I read that correctly? A. Correct. Q. And that would be the paper by Neuman titled "Transobturator vs. Single-Incision Suburethral Mini-Slings with 3-Year Followup? A. Correct. (Rosenzweig Exhibits 7 through 13 were marked for identification as of 2/4/16.) BY MR. ROSENBLATT: Q. I have gone ahead and premarked a number of exhibits here. I will go ahead and hand them to you all at once. These will be Exhibits 7 through 13.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And this is the type of study that surgeons in your field would review on a regular basis? A. Yes. Q. Is this the type of information that you would use to help counsel patients about either the TVT-O or the TVT Secur? A. I would not counsel patients on the TVT-O or the TVT Secur. Q. This is the type of paper that surgeons in your field would use to help them counsel patients about the risks and benefits of TVT-O and TVT Secur? MR. WALDENBERGER: Objection to form. You can answer. A. Doctors would not be counseling patients on TVT Secur currently. Q. When this was published in 2011? A. Correct.

35 (Pages 134 to 137)

1	Page 138		Page 140
1	that correctly?	1	versus zero percent prospectively. Thigh pain was
2	A. That's what the paper states.	2	transient and lasted no longer than two weeks."
3	Q. And do you disagree with that	3	Do you agree that there was a
4	conclusion?	4	statistically significant difference in the thigh
5	A. They showed a 31 percent vaginal pain,	5	and vaginal pain seen in this study?
6	31 percent thigh pain for the TVT-O group and an 8	6	A. That's what the authors found.
7	percent dyspareunia. I would disagree with the few	7	Q. And on the right side of the page it
8	adverse events.	8	says cure rate was 86.9 percent for the TVT-O group
9	Q. And you disagree with the conclusion	9	and 90.9 percent for the TVT Secur group. Do you
10	that both procedures were effective and had few	10	see that?
11	adverse events because of the high rate of vaginal	11	A. Yes.
12	and thigh pain observed in the TVT-O group?	12	Q. So at least in this study, which is an
13	A. And the 8 percent dyspareunia in the TVT	13	RCT following patients at three years, these
14	group I mean, TVT Secur group.	14	authors concluded that the cure rate for TVT Secur
15	Q. But you would agree that these authors	15	was 90.9 percent; is that correct?
16	determined or at least concluded that there were a	16	A. This is not an RCT. The study was an
17	few adverse effects?	17	open, prospective, non-randomized, two-arm trial,
18	A. That's what they state.	18	Page 770 under "Methods."
19	Q. If you turn to the second page, on the	19	Q. But you would agree in this two-armed
20	first paragraph in the top left towards the end it	20	comparative prospective study comparing the TVT-O
21	says, "The TVT Secur procedure is regarded by many,	21	to the TVT Secur, that these authors found at three
22	although not by all, as effective with little	22	years the cure rate for TVT Secur was 90.9 percent?
23	postoperative pain."	23	A. That's what they described.
24	Is that a statement that you agree with?	24	Q. You found this paper to be reliable?
	· ·	21	
	Page 139		Page 141
1	A. It is a statement that these authors	1 1	
		1	A. Yes.
2	make.	2	Q. And this paper you cited again for the
3	MR. WALDENBERGER: Where was that	2	Q. And this paper you cited again for the proposition that dyspareunia was higher in the TVT
3 4	MR. WALDENBERGER: Where was that statement again? I'm sorry. Thank you.	2 3 4	Q. And this paper you cited again for the proposition that dyspareunia was higher in the TVT Secur group than in the TVT-O group, right?
3 4 5	MR. WALDENBERGER: Where was that statement again? I'm sorry. Thank you. BY MR. ROSENBLATT:	2 3 4 5	Q. And this paper you cited again for the proposition that dyspareunia was higher in the TVT Secur group than in the TVT-O group, right? A. That dyspareunia was higher in the TVT
3 4	MR. WALDENBERGER: Where was that statement again? I'm sorry. Thank you. BY MR. ROSENBLATT: Q. And I understand that the authors made	2 3 4 5 6	Q. And this paper you cited again for the proposition that dyspareunia was higher in the TVT Secur group than in the TVT-O group, right? A. That dyspareunia was higher in the TVT secured group, yes, 8 percent versus zero percent.
3 4 5	MR. WALDENBERGER: Where was that statement again? I'm sorry. Thank you. BY MR. ROSENBLATT: Q. And I understand that the authors made that statement. That's why I just read it. My	2 3 4 5	 Q. And this paper you cited again for the proposition that dyspareunia was higher in the TVT Secur group than in the TVT-O group, right? A. That dyspareunia was higher in the TVT secured group, yes, 8 percent versus zero percent. Q. And as you just pointed out, this was
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36 (Pages 138 to 141)

	Page 142		Page 144
1	bottom left it says, "Vaginal mesh protrusion.	1	A. I'm speaking for what I would find
2	TVT-O, 1 patient or 1.4 percent, and TVT Secur,	2	unacceptable, yes.
3	zero, correct?	3	Q. And going back to the Neuman study, on
4	A. Correct.	4	the right side of Page 772 it says, "Common
5	Q. How do you explain the zero percent mesh	5	complications of former retropubic operations for
6	protrusion rate for TVT Secur in this study?	6	treatment of SUI such as pelvic and abdominal organ
7	MR. WALDENBERGER: Objection to the	7	injury and bladder penetration are rare with the
8	form. You can answer.	8	use of TVT-O and TVT Secur because the tape
9	A. As I described in my report, Dr. Neuman	9	introducers do not cross the retropubic area."
10	early on described a larger incision and a deeper	10	Did I read that correctly?
11	dissection that would avoid mucosal plication which	11	A. Yes.
12	might lead to vaginal wall penetration.	12	Q. Did you agree with that?
13	Q. So it would be fair to say that one of	13	A. The tape does not cross the retropubic
14	the contributing factors of a mesh erosion or	14	area with the TVT obturator. The TVT Secur is
15	exposure is surgical technique?	15	placed in a "U" fashion and is placed past the
16	A. For the TVT Secur, yes.	16	urogenital diaphragm. It would enter the
17	Q. Would that be different for the other	17	retropubic space.
18	TVT products?	18	Q. Do you agree with these authors that
19	A. It is specific for the TVT Secur, yes.	19	pelvic and abdominal organ injury and bladder
20	Q. So, as I understand your opinion,	20	penetration are rare with TVT Secur?
21	surgical technique can have strike that.	21	A. In my report, according to the Cochrane
22	As I understand your opinion, surgical	22	analysis done in 2014, adverse event profile is
23	technique could potentially be a factor in	23	noted to be significantly worse, consisting of a
24	contributing to mesh exposures with TVT Secur?	24	higher rate of operative blood loss, mesh exposure
	Page 143		Page 145
1		1	and bladder and urethral erosion.
1 2	A. Yes, because of what I described in my	1	and bradder and memial erosion
		2	
	report.	2	Q. So, you disagree with these authors,
3	Q. But that same logic would not carry over	3	Q. So, you disagree with these authors, correct?
3 4	Q. But that same logic would not carry over to the other TVT products?	3 4	Q. So, you disagree with these authors, correct?A. I'm describing what the Cochrane
3 4 5	Q. But that same logic would not carry over to the other TVT products?A. Because the TVT Secur device, the you	3 4 5	Q. So, you disagree with these authors, correct?A. I'm describing what the Cochrane analysis stated, that there is a increased risk of
3 4 5 6	Q. But that same logic would not carry over to the other TVT products? A. Because the TVT Secur device, the you can't really even call them trocars. The arrow tip	3 4 5 6	Q. So, you disagree with these authors, correct?A. I'm describing what the Cochrane analysis stated, that there is a increased risk of bladder and urethral erosion.
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Page 146 Page 148 inferior cure rates compared to TVT and TVT-O. Is 1 Secur, do you agree or disagree with that 1 2 2 that accurate. 3 3 A. Well, what they do is they describe that A. Yes. 4 there was less early postoperative vaginal pain and 4 Q. And you also mentioned earlier that this 5 5 early thigh pain. However, the dyspareunia, which was the study that showed a 19 percent mesh 6 would be somewhat later in occurrence because there 6 exposure with TVT Secur, correct? 7 7 is a certain period of time where you are going to A. Yes. 8 have the patient abstain from vaginal intercourse, 8 Q. And that you were not aware as you sit 9 9 that would be a later occurrence. here today of a study showing a higher rate of mesh 10 10 exposure with TVT Secur other than this study, They also describe that patients that 11 11 correct? had dyspareunia more often needed a surgical repair 12 for their dyspareunia. So, I would say that there 12 A. Not that I specifically recall. 13 would be more of a later complication associated 13 Q. And if you look towards the bottom of 14 with the TVT Secur. 14 the first page, it says, "Financial support for 15 this study was obtained from Ethicon Women's Health 15 Q. So, as I understand your testimony, you 16 16 and Urology, a Division of Ethicon, Inc., a Johnson wouldn't consider the postoperative vaginal and 17 groin pain seen in the TVT-O group as being a late 17 & Johnson company, as an investigator-initiated 18 or long-term complication, correct? 18 study." 19 A. Well, I think you've read earlier that 19 Do you see that? 20 that resolved within the first two weeks. 20 A. Correct. 21 Q. And do you share that same 21 Q. And would you agree although there is a 22 understanding? 22 potential for bias because of the financial 23 23 A. From this study? support, that does not mean that the study is 24 Q. Just in general. Would you consider 24 biased? Page 147 Page 149 1 that would be accurate? 1 A. Correct. 2 A. They are describing their data. Now, we 2 Q. And how did you go about discounting any 3 3 type of potential bias based on this financial do know from other studies, including the Petri support when you were using this data to cite in 4 4 study, that for midurethral slings the majority of 5 5 complications showed up after one year. Only 20 your expert report? 6 percent of midurethral sling complications show up 6 A. Again, I looked at the methods. They 7 within the first year, 60 percent show up within 7 received institutional review board approval. They 8 8 years 1 to 3. did a non-blinded randomized trial. They did a 9 9 Q. And this was a three-year study? adequate power analysis to determine what the 10 10 A. Correct. sample size that they would need. They did an 11 11 Q. So, there are some complication rates equivalent randomization. They described their 12 that are reported in this three-year study that you 12 methodology. They used multiple questionnaires to 13 agree with and there are some that you disagree 13 look at patient symptomatology, so that I found 14 14 with as far as being representative of average that the methodology used was very -- was 15 complications? 15 exceptional in the study. 16 16 Q. So in addition to the methodology being A. I would disagree that their zero -- zero 17 percent erosion rate is representative of average 17 exceptional in this study, you would consider this 18 complications. 18 study authoritative --19 19 Q. You can put that aside. Pull up A. Yes. 20 Exhibit 8, which is the Hota 2012 study. And 20 O. -- and reliable? 2.1 21 that's H-o-t-a. A. Yes. A. Yes. 22 22 Ο. And surgeons in the field would rely on 23 Q. And Doctor, I believe you cited the Hota 23 such studies?

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24

A. Yes.

24

study for the proposition of TVT Secur having

	Page 150		Page 152
1	Q. And this was published in the Female	1	Q. But you would agree that both TVT Secur
2	Pelvic Medicine and Reconstructive Surgery Journal?	2	and TVT-O resulted in improved quality of life in
3	A. Yes.	3	symptoms for these patients?
4	Q. Am I correct that you are still not	4	A. Based on the symptom questionnaires that
5	FPMRS certified?	5	were done.
6	A. Correct.	6	Q. And those are validated and reliable
7	Q. You have no intention of sitting for	7	questionnaires?
8	that certification?	8	A. Those are validated and reliable
9	A. Correct.	9	questionnaires. I would suggest that someone that
10	Q. Do you believe that there is a benefit	10	had a that they found a 19 percent erosion rate
11	for surgeons to obtain Female Pelvic Medicine	11	and a 19 percent subsequent reoperation rate and a
12	Reconstructive Surgery certification?	12	50 percent objective stress incontinence rate or,
13	A. Someone that is currently in fellowship,	13	excuse me, 55 percent objective stress incontinence
14	yes, because there are much more it's a much	14	rate would state that there probably would be a
15	more rigorous approval process. So, you have to do	15	lower degree of improvement of quality of life for
16	a fellowship, you have to do a written exam, you	16	the TVT Secur.
17	have to do a thesis, you have to take a	17	Q. Now I'm over on the right-hand column
18	subspecialty oral exam. So, it is a much more	18	starting with "midurethral." "Midurethral
19	rigorous certification process than what was	19	tension-free slings are minimally invasive
20	available from 2012 to 2015 for the, quote-unquote,	20	procedures that have been shown to have high
21	senior circuit. They just need to take a written	21	success rates and low overall complication rates."
22	exam.	22	Did I read that correctly?
23	Q. And you have not taken any exam to	23	A. And you are on which page now?
24	become certified, correct?	24	Q. First page.
	Page 151		Page 153
			rage 133
1	A. Correct.	1	MR. WALDENBERGER: Second paragraph.
1 2	A. Correct. Q. Now, looking at this study, towards the	1 2	
			MR. WALDENBERGER: Second paragraph.
2	Q. Now, looking at this study, towards the	2	MR. WALDENBERGER: Second paragraph. What was the sentence again?
2	Q. Now, looking at this study, towards the bottom of the results section it says both TVT-S	2	MR. WALDENBERGER: Second paragraph. What was the sentence again? MR. ROSENBLATT: First sentence.
2 3 4	Q. Now, looking at this study, towards the bottom of the results section it says both TVT-S which would be TVT Secur, correct?	2 3 4	MR. WALDENBERGER: Second paragraph. What was the sentence again? MR. ROSENBLATT: First sentence. MR. WALDENBERGER: Got it.
2 3 4 5	 Q. Now, looking at this study, towards the bottom of the results section it says both TVT-S which would be TVT Secur, correct? A. Yes. Q. So, both TVT-S and TVT-O resulted in improved quality of life and symptoms at 12 weeks. 	2 3 4 5	MR. WALDENBERGER: Second paragraph. What was the sentence again? MR. ROSENBLATT: First sentence. MR. WALDENBERGER: Got it. A. That's what they state.
2 3 4 5 6	Q. Now, looking at this study, towards the bottom of the results section it says both TVT-S which would be TVT Secur, correct? A. Yes. Q. So, both TVT-S and TVT-O resulted in	2 3 4 5 6	MR. WALDENBERGER: Second paragraph. What was the sentence again? MR. ROSENBLATT: First sentence. MR. WALDENBERGER: Got it. A. That's what they state. Q. And do you agree or disagree with that
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Now, looking at this study, towards the bottom of the results section it says both TVT-S which would be TVT Secur, correct? A. Yes. Q. So, both TVT-S and TVT-O resulted in improved quality of life and symptoms at 12 weeks. Did I read that correctly? A. Yes. Q. There was no difference between the groups for PFDI-20 or PFIQ-7. A similar pattern was seen at one year. Did I read that correctly? A. Yes. Q. And again, you said that you were impressed with the methodology of this study? A. Yes. Q. And so what this study showed is at one year, when comparing TVT-O to TVT Secur, that there was no statistically significant difference in the quality of life between the two, correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. WALDENBERGER: Second paragraph. What was the sentence again? MR. ROSENBLATT: First sentence. MR. WALDENBERGER: Got it. A. That's what they state. Q. And do you agree or disagree with that statement? A. Minimally invasive excuse me. "Midurethral tension-free slings are minimally invasive procedures that have a high success rate and how complication rate"? Q. Yes. A. I disagree with that, yes. Q. And towards the bottom starting with "In an attempt," it states, "In an attempt to further minimize postoperative complications and reduce the need for anesthesia, single-incision slings have been developed such as TVT Secur." Correct? Did I read that correctly? A. Yes, you did. Q. You would agree that that is a noble

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1	Page 154		Page 156
	to minimize postoperative complications and reduce	1	Q. And then it says mesh exposure, 8
2	the need for anesthesia. That's what the attempt	2	patients" strike that.
3	was.	3	It says mesh exposure, 8 patients or
4	Q. But that would be a good thing, correct?	4	19.1 percent for TVT Secur and zero patients or
5	A. To try to attempt that?	5	zero percent for TVT-O, correct?
6	Q. I'm asking you.	6	A. Correct.
7	MR. WALDENBERGER: I guess he is not	7	Q. What is your explanation for the zero
8	understanding your question, if I'm	8	percent mesh exposure for TVT-O?
9	understanding what you are asking him.	9	A. In the one-year followup there were no
10	A. Again, I'm not understanding the	10	patients that presented with an exposure with the
11	question.	11	TVT obturator.
12	MR. WALDENBERGER: Restate it.	12	Q. Based on the study are you able to
13	MR. ROSENBLATT: I will strike that.	13	determine why zero patients experienced a mesh
14	BY MR. ROSENBLATT:	14	exposure in the TVT-O group?
15	Q. "Limited data are available with regard	15	MR. WALDENBERGER: Objection to the
16	to this approach that mirrors the transobturator	16	form. You can answer.
17	sling but requires less dissection, uses a smaller	17	MR. ROSENBLATT: I hope this pause
18	amount of mesh and has no exit sites for the mesh.	18	isn't cutting into my time.
19	Early studies indicate a range of objective cure	19	MR. WALDENBERGER: I'm not tracking
20	rates from 70.3 percent to 87.5 percent."	20	the pause, but I won't hold it against you.
21	Did I read that correctly?	21	A. The authors theorize that the increase
22	A. Yes, you did.	22	in the incidence of mesh exposure in the TVT Secur
23	Q. And do you disagree with those findings?	23	group is due to the sharp edges of the TVT Secur
24	A. Well, we know from my report that the	24	introducer potentially creating more trauma to the
	Page 155		Page 157
1	incision size needed to be larger, the depth of	1	vaginal epithelium and results in a higher erosion
2	dissection needed to be increased in order to	2	rate.
3	attempt to minimize blood loss, minimize erosions	3	Q. Did I hear you correctly that they say
4	and minimize operative complications.	4	theorize?
5	Q. And if you turn to the bottom right-hand	5	
. ~	page, it says Page 43, I'm looking at Table 3, it	_	A. Correct.
6	page, it says rage 13, rill looking at ruble 3, it	6	A. Correct. Q. And so what that means is that they
	says, pain on postoperative day 7, TVT Secur, zero;		
б		6	Q. And so what that means is that they
6 7	says, pain on postoperative day 7, TVT Secur, zero;	6 7	Q. And so what that means is that they don't know but they are essentially guessing?
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40 (Pages 154 to 157)

Page 158 Page 160 1 edges could potentially create more trauma, 1 test it and then you draw a conclusion. 2 2 Q. Would you agree that theory would need 3 3 to be subsequently proven in randomized controlled A. Well, they document the sharp edges. 4 Q. Right, but the answer to my question is 4 trials? 5 5 they theorize that it could potentially create more A. Well, this is a randomized control 6 б trial, and they felt that the sharp edges trauma, correct? 7 MR. WALDENBERGER: Objection, asked 7 associated with the Secur was what they attributed 8 8 and answered. You can answer it again, if you their high erosion rate to. 9 9 understand what he is asking you. Q. But are you aware if they followed up 10 10 with additional testing to confirm that hypothesis A. They do say they theorize. They do say 11 11 they theorize, they do state we theorize and or theory? 12 potentially create more trauma, but they do 12 A. Not that I'm aware of. 13 document the sharp edges. 13 Q. And they attribute the laser-cut edge of 14 Q. Thank you, Doctor. So, as I understand 14 the TVT Secur to the higher exposure rate, but how 15 15 it, in this study these authors suggest a theory to do you explain the lack of dyspareunia or explain the 19 percent or the 5 patients who had a postoperative pain in the TVT Secur group? 16 16 17 mesh exposure in this study, but my original 17 A. Dyspareunia is not described in this 18 question to you was --18 report. They describe their findings from the 19 A. There were eight patients. 19 cumulative results of the quality of life 20 Q. Eight patients. I'm sorry. Thank you 20 questionnaires that were performed. 21 for correcting me. But my question was, how do you 21 Q. And these authors indicate towards the 22 explain the zero percent mesh exposure for the 22 bottom of Page 43, "The lower overall success of 23 23 TVT-O group? TVT Secur could be attributed to the difficulty 24 MR. WALDENBERGER: Objection, asked 24 that sometimes was encountered in the detachment of Page 159 Page 161 and answered. You can answer it again. 1 the introducer from the sling. During the 1 2 And Paul, are you asking him for his 2 introducer removal process, the original tensioning 3 interpretation or you are asking him to point 3 may have been compromised as the introducer was out in the article to you what their basis for 4 4 moved back and forth in an attempt to release the 5 5 sling from the introducer." zero was? MR. ROSENBLATT: I'm just asking as a 6 б Did I read that correctly? 7 7 surgeon who uses this study as support for his A. Yes. 8 8 opinions how he explains the zero percent mesh Q. So, is it your understanding that you 9 exposure for TVT-O, and I understand his 9 would attribute the failure rate in this study to 10 rationale for why the 19 percent might be 10 surgeon technique? 11 11 there for TVT Secur, but now I'm asking about MR. WALDENBERGER: That he would 12 the TVT-O. 12 attribute to it? 13 13 MR. WALDENBERGER: You can answer. MR. ROSENBLATT: Yeah, from reviewing 14 A. That is not discussed this in report. 14 this study. 15 Q. Do you have an opinion one way or the 15 MR. WALDENBERGER: He is asking your 16 other as to how these authors were able to obtain a 16 opinion. 17 zero percent mesh exposure rate for TVT-O in this 17 A. Right. No, I deal with that in my 18 study? 18 report. That is a design defect of the TVT Secur, 19 A. Not how these authors specifically were 19 difficulty in removing, releasing the Ethisorb 20 20 fleece end and detaching and removing the able to obtain a zero percent erosion rate. 21 21 Q. And if you were to rank levels of introducer. 22 evidence using the scientific method, how would you 22 Q. But you are aware of some surgeons not 23 rank hypothesis, theory, testing and conclusion? 23 having that difficulty, correct? A. Correct. 24 A. Well, you start with the hypothesis, you 24

	Page 162		Page 164
1	Q. And so this study attributes the lower	1	Q. I want to turn to Exhibit 9, which is
2	success rate to surgical technique, correct?	2	the Cornu study, and I believe you cited this study
3	A. No. They attribute it to the design	3	for the proposition in your report that TVT Secur
4	defect of the TVT Secur as I describe it in my	4	does not seem to be an appropriate option for
5	report.	5	first-line management of SUI in women?
6	Q. Turn to Page 44. In the right column	6	A. That's what the authors state.
7	it says, "Minimally invasive midurethral slings	7	Therefore, TVT Secur does not seem to be
8	have become the primary choice of many surgeons in	8	appropriate for SUI first-line management in women.
9	the treatment of SUI given their high long-term	9	Q. And was this study a randomized
10	success rates when compared with traditional	10	controlled trial?
11	pubovaginal slings and Burch colposuspension."	11	A. No.
12	Did I read that correctly?	12	Q. Was this study a long-term study?
13	A. You read that correctly.	13	A. The mean followup was 30 months or
14	Q. Do you disagree with the statement that	14	almost three years.
15	the authors made there?	15	Q. And you would agree that in a number of
16	MR. WALDENBERGER: There is a few	16	studies for the Burch colposuspension and the
17	statements there. Do you have one in	17	autologous fascial sling the authors combined their
18	particular?	18	cure rates with their improved rates to come to an
19	MR. ROSENBLATT: Sure. Let's break it	19	overall objective cure rate, correct?
20	down.	20	A. Yes. And to go back to your previous
21	BY MR. ROSENBLATT:	21	question, midurethral slings, Burch, in the
22	Q. Do you agree or disagree with the	22	prospective randomized long-term trials, there was
23	authors when they state that minimally invasive	23	no difference in the three 5-year studies there
24	midurethral slings have become the primary choice	24	was no difference in cure rate between Burch and
			was no difference in care rate between Baren and
	D 163		Dama 165
1	Page 163		Page 165
1	of many surgeons in the treatment of SUI?	1	midurethral slings.
2	of many surgeons in the treatment of SUI? A. That's what they state.	2	midurethral slings. Q. I'm going to try not to re-cover too
2	of many surgeons in the treatment of SUI? A. That's what they state. Q. I'm asking do you agree or disagree with	2	midurethral slings. Q. I'm going to try not to re-cover too much old ground, so I will keep my lips shut on
2 3 4	of many surgeons in the treatment of SUI? A. That's what they state. Q. I'm asking do you agree or disagree with those with that statement?	2 3 4	midurethral slings. Q. I'm going to try not to re-cover too much old ground, so I will keep my lips shut on that one.
2 3 4 5	of many surgeons in the treatment of SUI? A. That's what they state. Q. I'm asking do you agree or disagree with those with that statement? A. I think we have discussed that in	2 3 4 5	midurethral slings. Q. I'm going to try not to re-cover too much old ground, so I will keep my lips shut on that one. A. You had asked that question previously,
2 3 4 5 6	of many surgeons in the treatment of SUI? A. That's what they state. Q. I'm asking do you agree or disagree with those with that statement? A. I think we have discussed that in numerous depositions.	2 3 4 5 6	midurethral slings. Q. I'm going to try not to re-cover too much old ground, so I will keep my lips shut on that one. A. You had asked that question previously, and I just wanted to be responsive.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of many surgeons in the treatment of SUI? A. That's what they state. Q. I'm asking do you agree or disagree with those with that statement? A. I think we have discussed that in numerous depositions. Q. Do you disagree with that statement? A. I think we've discussed that the you know, the number of surgeons that are using midurethral slings in previous depositions. Q. Would you agree that there were a significant number of surgeons who were using single-incision slings such as TVT Secur? MR. WALDENBERGER: Objection to the form, that "significant" is a vague term. You can answer, if you can answer. A. There are surgeons that use single-incision slings to treat stress urinary incontinence. Q. And that's true today, correct? A. There are surgeons that are using single-incision slings under study protocols	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	midurethral slings. Q. I'm going to try not to re-cover too much old ground, so I will keep my lips shut on that one. A. You had asked that question previously, and I just wanted to be responsive. Q. And if you look at this study, they showed that 18 patients or 40 percent were cured while 8 patients or 18 percent were improved, correct? A. Correct. Q. And so if you add those together, that's a 68 percent cured/improved rate? A. 58 percent. Q. I'm sorry. 58 percent? A. Yes. Q. Now if you would turn to the next page, Page 158. First of all, Doctor, would you agree that this study is authoritative and reliable? A. Yes. Q. And surgeons in your field would rely on such studies?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	of many surgeons in the treatment of SUI? A. That's what they state. Q. I'm asking do you agree or disagree with those with that statement? A. I think we have discussed that in numerous depositions. Q. Do you disagree with that statement? A. I think we've discussed that the you know, the number of surgeons that are using midurethral slings in previous depositions. Q. Would you agree that there were a significant number of surgeons who were using single-incision slings such as TVT Secur? MR. WALDENBERGER: Objection to the form, that "significant" is a vague term. You can answer, if you can answer. A. There are surgeons that use single-incision slings to treat stress urinary incontinence. Q. And that's true today, correct? A. There are surgeons that are using	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	midurethral slings. Q. I'm going to try not to re-cover too much old ground, so I will keep my lips shut on that one. A. You had asked that question previously, and I just wanted to be responsive. Q. And if you look at this study, they showed that 18 patients or 40 percent were cured while 8 patients or 18 percent were improved, correct? A. Correct. Q. And so if you add those together, that's a 68 percent cured/improved rate? A. 58 percent. Q. I'm sorry. 58 percent? A. Yes. Q. Now if you would turn to the next page, Page 158. First of all, Doctor, would you agree that this study is authoritative and reliable? A. Yes. Q. And surgeons in your field would rely on

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	Page 166		Page 168
1	management," the second paragraph down, "Placement	1	BY MR. ROSENBLATT:
2	of a suburethral sling is the gold standard for the	2	Q under "Discussion," at the bottom of
3	management of SUI associated with urethral	3	that first paragraph it says, "TVT Secur minimizes
4	hypermobility. TVT and transobturator tape (TOT)	4	operative dissection and risk of injury of
5	are widely used in this indication with a high	5	periurethral elements in pelvic organs as well as
6	success rate and few complications."	6	the risk of nerve or adductor muscle damage."
7	Did I read that correctly?	7	Did I read that correctly?
8	A. Yes.	8	A. Yes, you read that correctly.
9	Q. Do you disagree with the author's	9	Q. And do you agree with that statement the
10	statement there that suburethral slings are the	10	authors made?
11	gold standard?	11	A. As I describe in my report, the incision
12	A. Yes.	12	site needs to be at least two centimeters with a
13		13	
	Q. What do you consider to be the current gold standard for the treatment of stress urinary	14	deep dissection in order to avoid dragging of
14 15	incontinence	15	periurethral and perivaginal tissue to decrease the risk of erosion.
16		16	
	A. There have been a number of	17	There is the Anders Hamer paper and also
17	Q the surgical treatment of stress		the Cochrane analysis that shows a higher risk of
18	urinary incontinence?	18	urethral and bladder erosion associated with the
19	A. There have been a number of articles	19	TVT Secur which are periurethral elements and
20	that have been written about the term "the gold	20	pelvic damage. I would agree that the TVT Secur
21	standard" and the lack of meaning that that term	21	does not go into the adductor muscles.
22	has.	22	Q. Doctor, the last paragraph on this page
23	Q. Doctor, would you consider	23	says, "Data analysis shows two different patterns
24	MR. WALDENBERGER: Hold on a second.	24	of failure. The first is a primary failure,
	Page 167		Page 169
			5
1	Were you done answering?	1	diagnosed at the first postoperative visit (13
1 2	Were you done answering? THE WITNESS: Yes.	1 2	
	•		diagnosed at the first postoperative visit (13
2	THE WITNESS: Yes.	2	diagnosed at the first postoperative visit (13 percent of our cases). This kind of event is well-known by all practitioners in the field of
2 3	THE WITNESS: Yes. MR. WALDENBERGER: Okay. BY MR. ROSENBLATT:	2	diagnosed at the first postoperative visit (13 percent of our cases). This kind of event is well-known by all practitioners in the field of sling surgery and is usually related to the
2 3 4	THE WITNESS: Yes. MR. WALDENBERGER: Okay. BY MR. ROSENBLATT: Q. So, Doctor, you would not use the term	2 3 4	diagnosed at the first postoperative visit (13 percent of our cases). This kind of event is well-known by all practitioners in the field of sling surgery and is usually related to the technical failure (sling misplacement), failure of
2 3 4 5	THE WITNESS: Yes. MR. WALDENBERGER: Okay. BY MR. ROSENBLATT: Q. So, Doctor, you would not use the term "gold standard" to describe the Burch	2 3 4 5	diagnosed at the first postoperative visit (13 percent of our cases). This kind of event is well-known by all practitioners in the field of sling surgery and is usually related to the
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2 3 4 5 6	THE WITNESS: Yes. MR. WALDENBERGER: Okay. BY MR. ROSENBLATT: Q. So, Doctor, you would not use the term "gold standard" to describe the Burch	2 3 4 5 6 7	diagnosed at the first postoperative visit (13 percent of our cases). This kind of event is well-known by all practitioners in the field of sling surgery and is usually related to the technical failure (sling misplacement), failure of the device itself, bad patient selection, learning
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1	Page 170		Page 172
	this study?	1	A. Correct.
2	A. What is my	2	Q. And the results showed quality of life
3	MR. WALDENBERGER: I object to the	3	scores through questionnaires improved in both
4	form. Why don't you ask it again. I think we	4	groups and were not statistically significant,
5	are both kind of confused by that one. Maybe	5	correct?
6	we will read it back.	6	A. Yes.
7	MR. ROSENBLATT: I will take care of	7	MR. WALDENBERGER: Actually, it says
8	it.	8	different, but okay. So you did not read that
9	BY MR. ROSENBLATT:	9	one correctly.
10	Q. These authors in this TVT Secur study	10	MR. ROSENBLATT: I was just asking
11	found zero erosions, correct?	11	him.
12	A. Yes.	12	MR. WALDENBERGER: Okay.
13	Q. What is your understanding as to how	13	BY MR. ROSENBLATT:
14	these authors could experience zero percent	14	Q. And it also says, "Initial postoperative
15	erosions in this study group?	15	groin pain was more prevalent in the TVT-O group.
16	A. They did not find an erosion in the	16	However, this resolved quickly with time."
17	three years that they were following these patients	17	Did I read that correctly?
18	on average.	18	A. Yes.
19	Q. And then under conclusions it says, "Our	19	Q. And do you disagree with their finding
20	midterm experience evaluating TVT Secur for SUI in	20	that postoperative groin pain resolves quickly with
21	women shows that this new technique is safe and	21	time after a TVT-O procedure?
22	quick and is associated with limited and mild side	22	A. Do I disagree with their findings?
23	effects."	23	Q. Yes.
24	Do you see that?	24	A. That's what they found.
	·		·
1	Page 171	1	Page 173
1	A. That's what they state, yes.	1	Q. Is that consistent with your
2	Q. Did you disagree with the author's	2	
. ≺		2	understanding of the body of literature on TVT-O?
3	conclusions that TVT Secur is a safe and quick	3	A. No. There is a group of patients who
4	operation?	4	A. No. There is a group of patients who have long-term, persistent groin pain associated
4 5	operation? A. Safe, no. Quick, yes. I agree with	4 5	A. No. There is a group of patients who have long-term, persistent groin pain associated with TVT-O.
4 5 6	operation? A. Safe, no. Quick, yes. I agree with quick. I don't agree with safe.	4 5 6	A. No. There is a group of patients who have long-term, persistent groin pain associated with TVT-O.Q. So you certainly wouldn't hold this
4 5 6 7	operation? A. Safe, no. Quick, yes. I agree with quick. I don't agree with safe. Q. And what is your understanding of how	4 5 6 7	 A. No. There is a group of patients who have long-term, persistent groin pain associated with TVT-O. Q. So you certainly wouldn't hold this paper out to support the statement that
4 5 6 7 8	operation? A. Safe, no. Quick, yes. I agree with quick. I don't agree with safe. Q. And what is your understanding of how quick the procedure is on average?	4 5 6 7 8	 A. No. There is a group of patients who have long-term, persistent groin pain associated with TVT-O. Q. So you certainly wouldn't hold this paper out to support the statement that postoperative groin pain quickly resolved with time
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4 5 6 7 8 9 10	operation? A. Safe, no. Quick, yes. I agree with quick. I don't agree with safe. Q. And what is your understanding of how quick the procedure is on average? A. I think they describe, most authors describe their operative time as less than 20 minutes.	4 5 6 7 8 9 10	A. No. There is a group of patients who have long-term, persistent groin pain associated with TVT-O. Q. So you certainly wouldn't hold this paper out to support the statement that postoperative groin pain quickly resolved with time after a TVT-O procedure, correct? A. The groin pain that they found in this study resolved quickly.
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44 (Pages 170 to 173)

1 A. Yes. 2 Q. And there are two different types of stechniques for the TVT Secur, correct? 4 A. Yes. 5 Q. And one would be the "U" which would follow the retropublic approach? 7 A. Yes. 8 Q. Even a the other would be the "H" or hammock, which would follow the obturator approach without going through the adductor muscles? 11 A. Yes. 12 Q. And this study evaluated the TVT hammock approach, correct? 13 approach, correct? 14 A. Yes. 15 Q. And what this study showed was that dyspareunia at one year was present in 14.3 percent of those with TVT Secur, correct? 16 those with TVT Secur, correct? 17 A. Yes. 28 Q. And so at least in this study, these authors found a higher rate of dyspareunia in TVT-O than they did with TVT Secur, correct? 19 why the patients in this study would have a lower dyspareunia rate in the TVT Secur group? 10 A. That's what these authors found. 11 Q. And if you look at postoperative groin pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur it shows zero, correct? 10 Q. Right. I'm on Table 2 - 11 A. Yes. 11 Q. And if you look at postoperative groin pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur; shows zero, correct? 12 A. Yes. 13 Q. Right. I'm on Table 2 - 14 A. Yes. 15 Q. In the interest of time we are going to skip over Exhibit 11. 16 If you could look at Exhibit 12, which is the Mostafa study? 17 HIB WITNESS: He has it. 18 BY MR. ROSENBLATT: 18 PAGE TVT Secur, correct? 21 A. Yes. 22 Q. And at least 12 of those randomized control trials evaluated TVT Secur, correct? 23 A. That's what these authors found. 24 Q. Other than their findings, you don't hold this patients and the valuated TVT Secur, correct? 25 A. Yes. 26 Q. Right. I'm on Table 2 - 27 A. They did not describe that in their report. 28 G. Right. I'm on Table 2 - 39 Q. Right. I'm on Table 2 - 40 Q. And are you suggesting that that statement is based on TVT Secur was officed, yes. 40 Q. And are you suggesting that that statement is based on TVT Secur was officed. A. Yes. 41 Q. And in TVT-O it was present in 6		Page 174		Page 176
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20 Q. And so at least in this study, these 21 authors found a higher rate of dyspareunia in TVT-O 22 than they did with TVT Secur, correct? 23 A. Yes. 24 Q. And do you have any understanding as to Page 175 1 why the patients in this study would have a lower 2 dyspareunia rate in the TVT Secur group? 3 A. That's what these authors found. 4 Q. Other than their findings, you don't 5 have an understanding as to why that might be, 6 correct? 7 A. They did not describe that in their 8 report. 9 Q. And if you look at postoperative groin 10 pain on Table 2, for TVT-O it shows 6 percent and 11 for TVT Secur it shows zero, correct? 12 A. Yes. 13 Q. Right. I'm on Table 2 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 20 And in TVT-O it was present in 6 percent 19 of the patients? 21 authors found a higher rate of dyspareunia in TVT-O 22 A. Yes. 22 Q. And at least 12 of those randomized 22 control trials evaluated TVT Secur, correct? 24 A. Yes. 25 Q. And if you look on Page 408 on the right-hand column, it says, "All RCTs reported improvement in QOL." That would be quality of life? 26 A. Yes. 27 Q. And if you look on Page 408 on the right-hand column, it says, "All RCTs reported improvement in QOL." That would be quality of life? 28 A. Yes. 29 So it says, "Nevertheless, all RCTs reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." 30 So is it your understanding there were no differences between single-incision mini-slings versus full-length mini-slings or full-length slings? 31 A. Yes. 42 A. When the data from TVT Secur was omitted, yes. 32 Q. And an Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1		·	19	O. And this is a meta-analysis that looked
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22 than they did with TVT Secur, correct? 23 A. Yes. 24 Q. And do you have any understanding as to Page 175 Page 175 Page 175 Page 177 why the patients in this study would have a lower dyspareunia rate in the TVT Secur group? A. That's what these authors found. Q. Other than their findings, you don't have an understanding as to why that might be, correct? A. They did not describe that in their report. Q. And if you look on Page 408 on the right-hand column, it says, "All RCTs reported improvement in QOL." That would be quality of life? A. Yes. Q. So it says, "Nevertheless, all RCTs reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." So is it your understanding there were no differences between single-incision mini-slings or full-length slings? A. Yes. Q. And are you suggesting that that A. Yes. Q. And in TVT-O it was present in 6 percent of the patients? Q. And in TVT Secur it was zero? 22 Q. And at least 12 of those randomized control trials evaluated TVT Secur, correct? A. Yes. Page 177 Q. And if you look on Page 408 on the right-hand column, it says, "All RCTs reported improvement in QOL." That would be quality of life? A. Yes. Q. So it says, "Nevertheless, all RCTs reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." So is it your understanding there were no differences between single-incision mini-slings or full-length slings? A. When the data from TVT Secur was omitted, yes. Q. And are you suggesting that that A. Yes. Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1	21	•		_
23 A. Yes. 24 Q. And do you have any understanding as to Page 175 Page 177 1 why the patients in this study would have a lower 2 dyspareunia rate in the TVT Secur group? 3 A. That's what these authors found. 4 Q. Other than their findings, you don't 5 have an understanding as to why that might be, 6 correct? 7 A. They did not describe that in their 8 report. 9 Q. And if you look at postoperative groin 10 pain on Table 2, for TVT-O it shows 6 percent and 11 for TVT Secur it shows zero, correct? 12 A. Can you repeat the question? 13 Q. Right. I'm on Table 2 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 20 A. Yes. 21 Q. And in TVT Secur it was zero? 22 control trials evaluated TVT Secur, correct? A. Yes. 24 A. Yes. 25 control trials evaluated TVT Secur, correct? A. Yes. 26 Q. And if you look on Page 408 on the 27 right-hand column, it says, "All RCTs reported 28 improvement in QOL." That would be quality of 39 life? 40 A. Yes. 41 A. Yes. 42 C. And if you look and postoperative groin 43 girll fier? 44 A. Yes. 45 Q. So it says, "Nevertheless, all RCTs 46 P. So it says, "Nevertheless, all RCTs 47 reported improvement in quality of life scores at 48 the followup compared with baseline with no 49 significant differences between SIMS versus SMUS." 40 So it your understanding there were 41 no differences between single-incision mini-slings or full-length 41 Slings? 42 A. When the data from TVT Secur was 43 control trials evaluated TVT Secur being excluded? 44 A. Yes. 45 Q. And in TVT Secur it was present in 6 percent 46 Q. And on Page 415 at the bottom right they 47 state, "All currently available single-incision 48 the followup compared with baseline with no 49 significant differences between single-incision 40 significant differences between single-incision 50 significant differences between single-incision 61 somfort? 62 Q. And an Page 415 at the bottom right they 63 state, "All currently available single-incision	22	- · · · · · · · · · · · · · · · · · · ·	22	Q. And at least 12 of those randomized
Page 175 Page 175 why the patients in this study would have a lower dyspareunia rate in the TVT Secur group? A. That's what these authors found. Q. Other than their findings, you don't have an understanding as to why that might be, correct? A. They did not describe that in their report. Q. And if you look on Page 408 on the improvement in QOL." That would be quality of life? A. Yes. Q. So it says, "Nevertheless, all RCTs reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." A. Can you repeat the question? A. Yes. Q. Right. I'm on Table 2 14 A. Yes. Q. And in TVT-O it was present in 6 percent of the patients? Q. And in TVT Secur it was zero? A. Yes. Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1		•	23	-
1 why the patients in this study would have a lower 2 dyspareunia rate in the TVT Secur group? 3 A. That's what these authors found. 4 Q. Other than their findings, you don't 5 have an understanding as to why that might be, 6 correct? 7 A. They did not describe that in their 8 report. 9 Q. And if you look at postoperative groin 10 pain on Table 2, for TVT-O it shows 6 percent and 11 for TVT Secur it shows zero, correct? 12 A. Can you repeat the question? 13 Q. Right. I'm on Table 2 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 2 Q. And in TVT Secur it was zero? 2 A. Yes. 2 Q. And in TVT Secur it was zero? 2 So it says, "Nevertheless, all RCTs 4 A. Yes. 6 Q. So it says, "Nevertheless, all RCTs 7 reported improvement in quality of life scores at 8 the followup compared with baseline with no 9 significant differences between SIMS versus SMUS." 10 So is it your understanding there were 11 no differences between single-incision mini-slings 12 versus full-length mini-slings or full-length 13 slings? 14 A. When the data from TVT Secur was 15 omitted, yes. 16 Q. And are you suggesting that that 17 statement is based on TVT Secur being excluded? 18 A. Yes. 19 Q. And on Page 415 at the bottom right they 19 state, "All currently available single-incision 19 mini-slings share the same type of material, type 1	24	Q. And do you have any understanding as to	24	
dyspareunia rate in the TVT Secur group? A. That's what these authors found. Q. Other than their findings, you don't have an understanding as to why that might be, correct? A. They did not describe that in their report. Q. And if you look at postoperative groin pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur it shows zero, correct? A. Can you repeat the question? Q. Right. I'm on Table 2 A. Yes. Q. And in TVT-O it was present in 6 percent A. Yes. Q. And on Page 415 at the bottom right they of the patients? Q. And in TVT Secur it was zero? 2 right-hand column, it says, "All RCTs reported improvement in QOL." That would be quality of life? A. Yes. Q. So it says, "Nevertheless, all RCTs reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." So is it your understanding there were no differences between single-incision mini-slings versus full-length mini-slings or full-length slings? A. When the data from TVT Secur was omitted, yes. Q. And are you suggesting that that A. Yes. Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1		Page 175		Page 177
dyspareunia rate in the TVT Secur group? A. That's what these authors found. Q. Other than their findings, you don't have an understanding as to why that might be, correct? A. They did not describe that in their report. Q. And if you look at postoperative groin pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur it shows zero, correct? A. Can you repeat the question? Q. Right. I'm on Table 2 A. Yes. Q. And in TVT-O it was present in 6 percent Q. And in TVT Secur it was zero? 2 right-hand column, it says, "All RCTs reported improvement in QOL." That would be quality of life? A. Yes. Q. So it says, "Nevertheless, all RCTs reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." So is it your understanding there were no differences between single-incision mini-slings versus full-length mini-slings or full-length slings? A. When the data from TVT Secur was omitted, yes. Q. And are you suggesting that that A. Yes. Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1	1	why the patients in this study would have a lower	1	Q. And if you look on Page 408 on the
A. That's what these authors found. Q. Other than their findings, you don't have an understanding as to why that might be, correct? A. They did not describe that in their report. Q. And if you look at postoperative groin pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur it shows zero, correct? A. Can you repeat the question? Q. Right. I'm on Table 2 A. Yes. Q. Right. I'm on Table 2 discomfort? A. Yes. Q. And in TVT-O it was present in 6 percent A. Yes. Q. And in TVT Secur it was zero? 3 improvement in QOL." That would be quality of 4 life? A. Yes. Q. So it says, "Nevertheless, all RCTs 7 reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." So is it your understanding there were no differences between single-incision mini-slings versus full-length mini-slings or full-length slings? A. When the data from TVT Secur was omitted, yes. Q. And are you suggesting that that A. Yes. Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1	2	·	2	
4 Q. Other than their findings, you don't 5 have an understanding as to why that might be, 6 correct? 6 Q. So it says, "Nevertheless, all RCTs 7 A. They did not describe that in their 8 report. 9 Q. And if you look at postoperative groin 10 pain on Table 2, for TVT-O it shows 6 percent and 11 for TVT Secur it shows zero, correct? 12 A. Can you repeat the question? 13 Q. Right. I'm on Table 2 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 20 A. Yes. 21 Q. And in TVT Secur it was zero? 22 So it says, "Nevertheless, all RCTs 25 A. Yes. 26 Q. So it says, "Nevertheless, all RCTs 26 P. A. Yes. 27 reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." 29 significant differences between SIMS versus SMUS." 20 No it says, "Nevertheless, all RCTs 20 A. Yes. 21 Nevertheless, all RCTs 20 A. Yes. 21 Nevertheless, all RCTs 21 RCTs 22 A. Yes. 24 A. Yes. 25 Q. And inform TVT Secure was omitified, yes. 26 Q. And are you suggesting that that 27 Secure being excluded? 28 A. Yes. 29 And on Page 415 at the bottom right they 20 State, "All currently available single-incision 21 mini-slings share the same type of material, type 1	3	* *	3	
have an understanding as to why that might be, correct? A. They did not describe that in their report. Q. And if you look at postoperative groin pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur it shows zero, correct? A. Can you repeat the question? Q. Right. I'm on Table 2 A. Yes. Q. So it says, "Nevertheless, all RCTs reported improvement in quality of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." So is it your understanding there were no differences between single-incision mini-slings versus full-length mini-slings or full-length slings? A. Yes. A. When the data from TVT Secur was omitted, yes. G. And are you suggesting that that statement is based on TVT Secur being excluded? A. Yes. Q. And in TVT-O it was present in 6 percent of the patients? Q. And in TVT Secur it was zero? A. Yes. Q. And in TVT Secur it was zero? A. Yes. Q. And in TVT Secur it was zero?	4		4	
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A. They did not describe that in their report. Q. And if you look at postoperative groin pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur it shows zero, correct? A. Can you repeat the question? Q. Right. I'm on Table 2 A. Yes. Q looking at the presence of groin discomfort? A. Yes. Q. And in TVT-O it was present in 6 percent Q. And in TVT-O it was zero? A. Yes. Q. And on Page 415 at the bottom right they and of life scores at the followup compared with baseline with no significant differences between SIMS versus SMUS." So is it your understanding there were no differences between single-incision mini-slings versus full-length mini-slings or full-length slings? A. When the data from TVT Secur was omitted, yes. Q. And are you suggesting that that A. Yes. Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1			6	Q. So it says, "Nevertheless, all RCTs
8 report. 9 Q. And if you look at postoperative groin 10 pain on Table 2, for TVT-O it shows 6 percent and 11 for TVT Secur it shows zero, correct? 12 A. Can you repeat the question? 13 Q. Right. I'm on Table 2 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 19 Q. And in TVT Secur it was zero? 20 A. Yes. 21 Q. And in TVT Secur it was zero? 22 time the followup compared with baseline with no 25 significant differences between SIMS versus SMUS." 26 So is it your understanding there were 27 no differences between single-incision mini-slings 28 versus full-length mini-slings or full-length 29 slings? 20 A. When the data from TVT Secur was 20 And are you suggesting that that 21 Statement is based on TVT Secur being excluded? 22 A. Yes. 23 Q. And on Page 415 at the bottom right they 24 state, "All currently available single-incision 25 mini-slings share the same type of material, type 1	7	A. They did not describe that in their	7	
9 Q. And if you look at postoperative groin 10 pain on Table 2, for TVT-O it shows 6 percent and 11 for TVT Secur it shows zero, correct? 12 A. Can you repeat the question? 13 Q. Right. I'm on Table 2 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 10 So is it your understanding there were 11 no differences between single-incision mini-slings 12 versus full-length mini-slings or full-length 13 slings? 14 A. When the data from TVT Secur was 15 omitted, yes. 16 Q. And are you suggesting that that 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 19 Q. And on Page 415 at the bottom right they 20 A. Yes. 20 state, "All currently available single-incision 21 mini-slings share the same type of material, type 1	8	-	8	the followup compared with baseline with no
pain on Table 2, for TVT-O it shows 6 percent and for TVT Secur it shows zero, correct? 11 for TVT Secur it shows zero, correct? 12 A. Can you repeat the question? 13 Q. Right. I'm on Table 2 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 10 So is it your understanding there were no differences between single-incision mini-slings or full-length slings? 12 versus full-length mini-slings or full-length slings? 13 slings? 14 A. When the data from TVT Secur was omitted, yes. 15 Q. And are you suggesting that that statement is based on TVT Secur being excluded? 18 A. Yes. 19 Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1	9	•	9	significant differences between SIMS versus SMUS."
11 for TVT Secur it shows zero, correct? 12 A. Can you repeat the question? 13 Q. Right. I'm on Table 2 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 10 And in TVT Secur it was zero? 11 no differences between single-incision mini-slings versus full-length mini-slings or full-length slings? 12 versus full-length mini-slings or full-length slings? 13 slings? 14 A. When the data from TVT Secur was omitted, yes. 15 Q. And are you suggesting that that statement is based on TVT Secur being excluded? 18 A. Yes. 19 Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1	10	pain on Table 2, for TVT-O it shows 6 percent and	10	_
13 slings? 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 19 Q. And in TVT Secur it was zero? 10 A. Yes. 20 And in TVT Secur it was zero? 21 Q. And in TVT Secur it was zero? 21 Slings? 22 A. When the data from TVT Secur was omitted, yes. 23 Omitted, yes. 24 A. When the data from TVT Secur was omitted, yes. 25 Q. And are you suggesting that that statement is based on TVT Secur being excluded? 26 A. Yes. 27 Q. And on Page 415 at the bottom right they state, "All currently available single-incision mini-slings share the same type of material, type 1	11	-	11	no differences between single-incision mini-slings
13 slings? 14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 19 Q. And in TVT Secur it was zero? 10 A. Yes. 11 A. Yes. 12 Q. And on Page 415 at the bottom right they 13 slings? 14 A. When the data from TVT Secur was 15 omitted, yes. 16 Q. And are you suggesting that that 17 statement is based on TVT Secur being excluded? 18 A. Yes. 19 Q. And on Page 415 at the bottom right they 20 state, "All currently available single-incision 21 mini-slings share the same type of material, type 1	12	A. Can you repeat the question?	12	versus full-length mini-slings or full-length
14 A. Yes. 15 Q looking at the presence of groin 16 discomfort? 17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 10 A. Yes. 11 A. When the data from TVT Secur was omitted, yes. 12 O. And are you suggesting that that statement is based on TVT Secur being excluded? 18 A. Yes. 19 Q. And on Page 415 at the bottom right they state, "All currently available single-incision 20 A. Yes. 21 Q. And in TVT Secur it was zero? 22 mini-slings share the same type of material, type 1	13	Q. Right. I'm on Table 2	13	slings?
16 discomfort? 18 Q. And are you suggesting that that 17 statement is based on TVT Secur being excluded? 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 19 Q. And on Page 415 at the bottom right they 20 A. Yes. 20 state, "All currently available single-incision 21 Q. And in TVT Secur it was zero? 21 mini-slings share the same type of material, type 1	14	-	14	
17 A. Yes. 18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 19 A. Yes. 19 Q. And on Page 415 at the bottom right they 20 A. Yes. 21 Q. And in TVT Secur it was zero? 21 mini-slings share the same type of material, type 1	15	Q looking at the presence of groin	15	omitted, yes.
18 Q. And in TVT-O it was present in 6 percent 19 of the patients? 20 A. Yes. 21 Q. And in TVT Secur it was zero? 18 A. Yes. 29 Q. And on Page 415 at the bottom right they 20 state, "All currently available single-incision 21 mini-slings share the same type of material, type 1	16	discomfort?	16	Q. And are you suggesting that that
19 of the patients? 20 A. Yes. 21 Q. And on Page 415 at the bottom right they 22 state, "All currently available single-incision 23 mini-slings share the same type of material, type 1	17	A. Yes.	17	statement is based on TVT Secur being excluded?
19Of the patients?19Q. And on Page 415 at the bottom right they20A. Yes.20state, "All currently available single-incision21Q. And in TVT Secur it was zero?21mini-slings share the same type of material, type 1	18	Q. And in TVT-O it was present in 6 percent	18	A. Yes.
21 Q. And in TVT Secur it was zero? 21 mini-slings share the same type of material, type 1	19		19	Q. And on Page 415 at the bottom right they
	20	A. Yes.	20	state, "All currently available single-incision
	21	Q. And in TVT Secur it was zero?	21	mini-slings share the same type of material, type 1
22 A. Yes. 22 polypropylene, and the insertion technique through	22	A. Yes.	22	polypropylene, and the insertion technique through
Q. And vaginal erosion was zero percent in 23 a single vaginal incision; however, they differ in	23	Q. And vaginal erosion was zero percent in	23	a single vaginal incision; however, they differ in
24 the TVT-O group, correct? 24 the type/robustness of the anchorage mechanism	24	the TVT-O group, correct?	24	the type/robustness of the anchorage mechanism

45 (Pages 174 to 177)

	Page 178		Page 180
1	used."	1	A. Yes.
2	Did I read that correctly?	2	Q. And it analyzed a variety of many
3	A. You read that correctly, yes.	3	slings, including TVT Secur, MiniArc, Ajust,
4	Q. Would you agree that this study did not	4	Needless, Ophira, tissue fixation systems and
5	evaluate any partially absorbable slings of any	5	CureMesh, correct?
6	type?	6	A. Yes.
7	A. Correct.	7	Q. And one thing that these authors
8	Q. Would you agree from a safety	8	concluded was that significant difference in
9	perspective that it would be preferable to have an	9	fixation mechanisms may influence outcomes?
10	absorbable fixation tip as opposed to a permanent	10	A. That's what they describe.
11	fixation tip?	11	Q. In the studies that we just looked at,
12	-	12	Neuman, Hota, Cornu, Maslow, how many of those are
13	A. From what perspective?	13	cited in this Cochrane review?
	Q. Safety.		
14	A. If it was shown that an absorbable	14	And in the interest of time, Doctor, I
15	fixation tip had a greater safety profile, then it	15	will just represent to you that the only study I
16	would be safer to have an absorbable fixation tip.	16	saw was the Hota study.
17	Q. On Page 423 towards the bottom left of	17	A. Yeah, I didn't see Neuman being referred
18	the page these authors state, "Interestingly,	18	to. What was the other one. Maslow?
19	despite the exclusion of TVT Secur, single-incision	19	Q. Maslow and Cornu.
20	mini-slings still had a trend, albeit	20	A. Well, Maslow might have come out too
21	insignificant, towards higher rates of repeat	21	late for this 2014 Cochrane analysis, and I
22	continence surgery."	22	wouldn't expect Cornu because it was not a
23	Did I read that correctly?	23	randomized control trial.
24	MR. WALDENBERGER: Where was that	24	Q. So, just because a study doesn't meet
	Page 179		Page 181
1	Page 179 again? I'm sorry.	1	Page 181 the qualitative criteria for inclusion in a
1 2		1 2	
	again? I'm sorry.		the qualitative criteria for inclusion in a
2	again? I'm sorry. MR. ROSENBLATT: Bottom left, not the	2	the qualitative criteria for inclusion in a Cochrane review doesn't mean that you wouldn't rely
2 3	again? I'm sorry. MR. ROSENBLATT: Bottom left, not the last paragraph but up a little bit.	2	the qualitative criteria for inclusion in a Cochrane review doesn't mean that you wouldn't rely on it for certain purposes to support your
2 3 4	again? I'm sorry. MR. ROSENBLATT: Bottom left, not the last paragraph but up a little bit. MR. WALDENBERGER: "Unlike other"?	2 3 4	the qualitative criteria for inclusion in a Cochrane review doesn't mean that you wouldn't rely on it for certain purposes to support your opinions, correct?
2 3 4 5	again? I'm sorry. MR. ROSENBLATT: Bottom left, not the last paragraph but up a little bit. MR. WALDENBERGER: "Unlike other"? MR. ROSENBLATT: Yes, the bottom of	2 3 4 5	the qualitative criteria for inclusion in a Cochrane review doesn't mean that you wouldn't rely on it for certain purposes to support your opinions, correct? A. Or to discount my opinions.
2 3 4 5 6	again? I'm sorry. MR. ROSENBLATT: Bottom left, not the last paragraph but up a little bit. MR. WALDENBERGER: "Unlike other"? MR. ROSENBLATT: Yes, the bottom of that paragraph.	2 3 4 5 6	the qualitative criteria for inclusion in a Cochrane review doesn't mean that you wouldn't rely on it for certain purposes to support your opinions, correct? A. Or to discount my opinions. Q. Correct? A. Correct.
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46 (Pages 178 to 181)

	Page 182		Page 184
1	all TVT Secur?	1	Q. "A statistically significant difference
2	A. For this section, yes.	2	favored single-incision slings in the latter case
3	Q. And the authors of this Cochrane review	3	only. Although uncommon, women were significantly
4	found that to be 6 percent mesh exposure rate for	4	less likely to have long-term pain after a
5	TVT Secur?	5	single-incision sling than after a transobturator
6	A. Based on the studies that they included	6	sling and the overall result favored
7	in their review, yes.	7	single-incision slings," correct?
8	Q. And under "Postoperative pain or	8	A. That's what they state.
9	discomfort" it states, "The overall result was	9	Q. And the long-term pain or discomfort
10	statistically significant, favoring single-incision	10	rate that they list for mini-slings is 0.5 percent,
11	slings," correct?	11	correct?
12	A. That's what they state.	12	A. That's what they describe.
13	Q. And this Cochrane review is	13	Q. And you would certainly take the
14	authoritative and reliable, correct?	14	position that an average figure for a complication
15	A. Yes.	15	listed in the meta-analysis would be more reliable
16	Q. And surgeons in your field would rely on	16	than the complication rate pulled from one
17		17	particular study, correct?
18	such meta-analyses in reviewing complication rates	18	
19	for various procedures? A. Yes.	19	A. Meta-analysis pools data and therefore,
20	A. Tes. Q. And is it your understanding that	20	depending on which studies they looked at, that
21	•	21	would give you more robust data than from one
22	Cochrane reviews are on the top of the pyramid of evidence-based medicine?	22	single study.
23		23	MR. ROSENBLATT: I will take a quick break.
24	A. They are high up on the pyramid, yes.	24	MR. WALDENBERGER: Sure.
<u> </u>	Q. And a little further down it says, "The	24	
	Page 183		D 10FI
			Page 185
1	combined overall result showed that women had less	1	(Rosenzweig Exhibits 14 through 20
2	combined overall result showed that women had less short-term pain or discomfort after a	2	(Rosenzweig Exhibits 14 through 20 were marked for identification as
2	combined overall result showed that women had less short-term pain or discomfort after a single-incision sling," correct?	2	(Rosenzweig Exhibits 14 through 20 were marked for identification as of 2/4/16.)
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	combined overall result showed that women had less short-term pain or discomfort after a single-incision sling," correct? A. Yes. Q. And I think you might have answered this, but I can't recall. You would agree that postoperative or reducing postoperative pain would be a benefit, correct? MR. WALDENBERGER: I object to the form. You can answer. A. Yes. Q. And then a little further down it says, "Long-Term Pain or Discomfort." Do you see that section? A. Yes. Q. And it says, "This was rare," and when it says "this," they are referring to long-term pain or discomfort? A. Based on the studies that they looked at. Q. So the authors conclude that long-term	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	(Rosenzweig Exhibits 14 through 20 were marked for identification as of 2/4/16.) (Recess taken, 1:20 - 1:34 p.m.) (Mr. Campbell re-entered the deposition room.) BY MR. ROSENBLATT: Q. Doctor, we just took a quick break. I am going to hand you what's been marked as Exhibit 14. A. Yes. Q. Do you understand this to be the TVT Secur instructions for use? A. Yes. Q. I would like you to turn to the sorry. Let me back up. When was the first time you reviewed the TVT Secur instructions for use? A. I don't recall if I saw this book when the product was first being introduced and I was being detailed on it. I think that might have been the first time that I saw it.

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Page 186 Page 188 implanted a TVT Secur? 1 1 Q. And is your interpretation of that 2 A. Correct. 2 warning there, that under-correction or not 3 3 Q. Do you know if you have ever discussed providing enough tensioning could then result in no 4 the TVT Secur implantation with any surgeon who has 4 cure of incontinence? 5 5 performed the TVT Secur? A. That is one of the defects of the 6 6 A. Not that I specifically recall. device, yes. 7 7 Q. And you have never attended any Q. But is that how you understand that warning? 8 professional education training of any type on the 8 9 9 TVT Secur, correct? A. That is part of the warning. 10 10 A. I might have been in a grand rounds Q. Put that away. I would like you to look 11 where it was discussed. 11 at what's been marked as Exhibit 15. Are you 12 Q. But you don't recall? 12 familiar with Dr. Walters and Dr. Weber? 13 A. I don't recall. 13 A. I know Dr. Walters. I have met 14 Q. You have certainly never attended any 14 Dr. Weber in the past. professional education that Ethicon sponsored 15 15 Q. And would you consider them respected regarding the TVT Secur, correct? 16 16 physicians in their field? 17 A. Correct. 17 A. Yes. 18 Q. And if you look at Bates ending in 576, 18 Q. And on the front page of this article it 19 it reads, "This package insert is designed to 19 states, "Almost all surgical procedures for stress provide instructions for use of the Gynecare TVT 20 urinary continence performed today involve 20 21 Secur system, including the device and inserters. 21 placement of a retropubic or transobturator 22 It is not a comprehensive reference to surgical 22 midurethral synthetic sling," correct? 23 technique for correcting SUI (stress urinary 23 A. That's what they state. 24 incontinence). Only physicians trained in the 24 Q. Is that still true today? Or strike Page 187 Page 189 surgical treatment of stress urinary incontinence that. This was published in 2012? 1 2 should use the product. These instructions are 2 A. That's when it was published, yes. 3 3 intended for general use of the product. Q. And if you turn the page, they state, 4 4 "Although Burch colposuspension and the pubovaginal Variations in use may occur in specific procedures 5 5 due to individual technique in patient anatomy." fascial sling procedure are effective for both Did I read that correctly? 6 primary and recurrent SUI, they are more invasive 6 7 7 A. Yes. than the midurethral slings, cause more voiding 8 8 Q. And would you agree that results -- or dysfunction and have significantly longer recovery 9 9 times, making them less attractive for most primary strike that. 10 10 Would you agree with me that there and recurrent cases of SUI." 11 11 are -- strike that. Did I read that correctly? 12 Would you agree with me that procedural 12 A. You read that correctly. 13 Q. And do you disagree with Dr. Walters and 13 differences in technique and patient anatomy can Dr. Weber when they made that statement in this 14 affect both complications and success rates for TVT 14 15 Secur? 15 article? 16 A. Well, as I described in my report, that 16 A. Regarding voiding dysfunction, there are 17 is one of the defects of the TVT Secur. 17 certain references that show more voiding 18 Q. And if you turn to Page 22, Bates ending 18 dysfunction, certain references show less return to 19 19 the operating room for obstructed voiding. So, I in 589, if you look at the last bullet point under 20 "Adverse Reactions," it reads, "Under-correction or 20 would disagree with that statement. 21 21 Q. Would you disagree that the Burch and incorrect placement may result in incomplete or no 22 22 relief from urinary incontinence." autologous sling have significantly longer recovery 23 Did I read that correctly? 23 times than midurethral slings? 24 A. They have longer recovery times. 24 A. That's what it states.

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Page 190	Page 192
1 Q. And you would agree that a shorter 1 Q. A	and this is the type of systematic
	meta-analysis that you would consider to
	itative and reliable?
4 MR. WALDENBERGER: Objection, asked 4 A. Y	es.
•	and this is also the type of systematic
•	d meta-analysis that you would put at the
	pyramid of evidence-based medicine?
	is high on the pyramid of
	based medicine, and we have also discussed
	ultiple different occasions.
	and certainly surgeons in your field
	y on such meta-analyses?
13 gynecology or urology residence programs." 13 A. Y	•
	low, Doctor, I know we have been through
	e in the past, but what I want to do is
	the mini-slings.
17 still taught in residency programs at Rush 17 A. Y	_
	you could, turn to what's listed at
	n of this as I think 1.e5, Table 1, and I
*	up the TVT Secur RCTs that were included in
7.2. 9	sis, and I counted 14 TVT Secur RCTs.
	appear to be accurate?
23 sling at Rush? 23 A. Y	
	and if you turn to Table 3, what the
Page 191	Page 193
1 Q. Do you have any idea what other 1 authors d	lid here is they accumulated and analyzed
	poking at various complication rates of
	ncontinence procedures?
4 Q. And do you know whether or not the 4 A. Y	_
	And the first one I want to talk about
	ted blood loss greater than 200
	s. Do you see that at the top of
8 A. I do not think TVT Secur was available 8 Table 3?	
	went a few pages.
-	
10 Q. Do you know one way or the other?	MR. WALDENBERGER: 1.e7.
10 Q. Do you know one way or the other? 10 M 11 A. I do not think the TVT Secur has ever 11 A. Y	MR. WALDENBERGER: 1.e7. Yes.
10Q. Do you know one way or the other?10M11A. I do not think the TVT Secur has ever11A. Y12been available at our hospital.12Q. A	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent?
10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 10 M 11 A. Y 12 Q. A	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes.
10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 14 this study? 10 M A. Y 11 A. Y 12 Q. A 13 Q. Pull up Exhibit 16. Do you recognize 14 Q. A	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes. And when we say 1.1 percent, that column
10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 14 this study? 15 A. Yes. 10 M. A. Y. Y. A. Y. A. Y. Y. A. Y	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes.
10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 14 this study? 15 A. Yes. 16 Q. And this is a systematic review 10 M. A. Y. Y. A. Y. A. Y. Y. Y. A. Y. Y. Y. A. Y. Y. Y. A. Y.	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes. And when we say 1.1 percent, that column mmary estimate of incidence? Yes.
10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 14 this study? 15 A. Yes. 16 Q. And this is a systematic review 17 performed by the Society of Gynecologic Surgeons, 10 M. A. Y. Y. A. Y. A. Y. Y. Y. A. Y.	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes. And when we say 1.1 percent, that column mmary estimate of incidence? Yes. And if we look down at hematoma, the
10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 14 this study? 15 A. Yes. 16 Q. And this is a systematic review 17 performed by the Society of Gynecologic Surgeons, 10 M. A. Y. Y. A. Y. A. Y. Y. Y. A. Y.	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes. And when we say 1.1 percent, that column mmary estimate of incidence? Yes. And if we look down at hematoma, the g has an incidence rate of 0.85 percent?
10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 14 this study? 15 A. Yes. 16 Q. And this is a systematic review 17 performed by the Society of Gynecologic Surgeons, 18 also known as SGS, correct? 19 A. Yes. 10 M. A. Y.	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes. And when we say 1.1 percent, that column mmary estimate of incidence? Yes. And if we look down at hematoma, the g has an incidence rate of 0.85 percent? Yes.
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10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 14 this study? 15 A. Yes. 16 Q. And this is a systematic review 17 performed by the Society of Gynecologic Surgeons, 18 also known as SGS, correct? 19 A. Yes. 20 Q. The lead author is Schimpf? 21 the Burch	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes. And when we say 1.1 percent, that column mmary estimate of incidence? Yes. And if we look down at hematoma, the g has an incidence rate of 0.85 percent? Yes. And that's less than the 1.4 percent for h and the 2.2 percent for the pubovaginal
10 Q. Do you know one way or the other? 11 A. I do not think the TVT Secur has ever 12 been available at our hospital. 13 Q. Pull up Exhibit 16. Do you recognize 14 this study? 15 A. Yes. 16 Q. And this is a systematic review 17 performed by the Society of Gynecologic Surgeons, 18 also known as SGS, correct? 19 A. Yes. 20 Q. The lead author is Schimpf? 21 A. Yes. 22 Lathe Burch 22 Sling, correct.	MR. WALDENBERGER: 1.e7. Yes. And for mini-sling it shows 1.1 percent? Yes. And when we say 1.1 percent, that column mmary estimate of incidence? Yes. And if we look down at hematoma, the g has an incidence rate of 0.85 percent? Yes. And that's less than the 1.4 percent for h and the 2.2 percent for the pubovaginal

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Ī	Page 194		Page 196
1	these numbers?	1	Q. And 1.6 percent in the pubovaginal sling
2	A. The rate of transfusion was higher in	2	group, correct?
3	the mini-sling than Burch, and they don't even	3	A. And 2.7 percent for the obturator group.
4	discuss the estimated blood loss with the Burch	4	Q. Under mesh exposure it says mini-sling,
5	procedure.	5	2 percent?
6	Q. And when you said it is higher, the	6	A. Yes.
7	transfusion rate is higher in the mini-sling, the	7	Q. And in fairness, Burch, zero percent,
8	transfusion rate for the mini-sling was 0.51	8	correct?
9	percent?	9	A. Correct.
10	A. Yes, and it was zero for Burch.	10	Q. Retropubic, 1.4 percent?
11	Q. And if we look at dyspareunia, for	11	A. That's what they state.
12	mini-sling the incidence rate is 0.74 percent,	12	Q. Obturator, 2.2 percent?
13	correct?	13	A. Yes.
14	A. Yes.	14	Q. Pubovaginal, 5.4 percent?
15	Q. And the pubovaginal sling is 0.99	15	A. That's what they state.
16	percent, correct?	16	Q. And you have no reason to disagree with
17	A. Yes, and there is no dyspareunia with	17	those figures, do you?
18	the Burch procedure.	18	A. Based on the studies that they have
19	Q. But you wouldn't necessarily agree with	19	reviewed.
20	the statement you just made, correct?	20	Q. And wound healing or strike that.
21	A. According to the Schimpf review.	21	Wound infection, mini-sling was 0.31
22	Q. I'm asking you so as I understand it,	22	percent?
23	dyspareunia is not listed for the Burch in this	23	A. And there were no wound infections for
24	review, but that doesn't mean that it just doesn't	24	the Burch.
	Page 195		Page 197
1	exist for the Burch, correct?	1	Q. It actually shows 7 percent for the
2	A. So, then what you are stating is by that	2	Burch?
3	same logic, because dyspareunia as stated with the	3	A. Excuse me. Yes.
4	mini-sling is 0.74 percent, that doesn't mean that	4	
5	the rate of dyspareunia isn't 10 percent like we		O. And 2.6 percent for pubovaginal slings?
		5	Q. And 2.6 percent for pubovaginal slings?A. Yes.
6		5 6	A. Yes.
6 7	found before.		A. Yes.Q. And for urinary tract infections, the
7	found before. Q. Well, I'm just asking you, would you	6 7	A. Yes. Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent?
	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't	6	A. Yes.Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent?A. Yes.
7 8	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of	6 7 8	 A. Yes. Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent? A. Yes. Q. And that would be lower than pubovaginal
7 8 9 10	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of dyspareunia, would you?	6 7 8 9	A. Yes.Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent?A. Yes.
7 8 9	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of dyspareunia, would you?	6 7 8 9 10	 A. Yes. Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent? A. Yes. Q. And that would be lower than pubovaginal sling at 4.2 percent and Burch at 5.9 percent,
7 8 9 10 11	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of dyspareunia, would you? A. It says retropubic slings have a zero percent risk of dyspareunia or have zero percent	6 7 8 9 10 11	 A. Yes. Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent? A. Yes. Q. And that would be lower than pubovaginal sling at 4.2 percent and Burch at 5.9 percent, correct? A. That's what they state.
7 8 9 10 11 12	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of dyspareunia, would you? A. It says retropubic slings have a zero	6 7 8 9 10 11	 A. Yes. Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent? A. Yes. Q. And that would be lower than pubovaginal sling at 4.2 percent and Burch at 5.9 percent, correct? A. That's what they state.
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7 8 9 10 11 12 13	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of dyspareunia, would you? A. It says retropubic slings have a zero percent risk of dyspareunia or have zero percent dyspareunia, so they didn't even have the Burch	6 7 8 9 10 11 12 13	 A. Yes. Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent? A. Yes. Q. And that would be lower than pubovaginal sling at 4.2 percent and Burch at 5.9 percent, correct? A. That's what they state. Q. And bowel injury shows a 0.74 percent incidence rate for mini-slings into 3.13 incidence
7 8 9 10 11 12 13 14 15	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of dyspareunia, would you? A. It says retropubic slings have a zero percent risk of dyspareunia or have zero percent dyspareunia, so they didn't even have the Burch there, and so therefore, I would say that there was zero percent risk of dyspareunia.	6 7 8 9 10 11 12 13 14	 A. Yes. Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent? A. Yes. Q. And that would be lower than pubovaginal sling at 4.2 percent and Burch at 5.9 percent, correct? A. That's what they state. Q. And bowel injury shows a 0.74 percent incidence rate for mini-slings into 3.13 incidence rate for the Burch, correct?
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	found before. Q. Well, I'm just asking you, would you and I appreciate your logic there, but you wouldn't suggest that the Burch has a zero percent rate of dyspareunia, would you? A. It says retropubic slings have a zero percent risk of dyspareunia or have zero percent dyspareunia, so they didn't even have the Burch there, and so therefore, I would say that there was zero percent risk of dyspareunia. Q. Is it fair to say that you disagree with the incidence rate of the mini-sling, 0.74 percent dyspareunia? A. I would disagree with that by the same logic that we talked about the Burch procedure. Q. And the complication of return to	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. And for urinary tract infections, the mini-sling had an incidence rate of 3.6 percent? A. Yes. Q. And that would be lower than pubovaginal sling at 4.2 percent and Burch at 5.9 percent, correct? A. That's what they state. Q. And bowel injury shows a 0.74 percent incidence rate for mini-slings into 3.13 incidence rate for the Burch, correct? A. And that Burch was based on one study which a laparoscopic Burch. Q. But that's what they report here? A. Yes. Q. And for nerve injury, mini-sling shows zero percent?

50 (Pages 194 to 197)

	Page 198		Page 200
1	A. Yes.	1	rate?
2	Q. In fairness, Burch shows a 4.3 percent	2	A. Yes.
3	rate?	3	Q. And with the obturator they show a 16
4	A. Yes.	4	percent incidence rate, correct?
5	Q. And the pubovaginal, 8.6 percent,	5	A. Yes.
6	correct?	6	Q. And with bladder perforation the authors
7	A. That's what they state.	7	conclude the mini-slings have a 0.85 percent
8	Q. And retention lasting longer than six	8	incidence rate?
9	weeks postoperatively, they have a rate of 2.1	9	A. That's what they found.
10	percent for the mini-sling, correct? I'm sorry.	10	Q. And that's lower than the pubovaginal at
11	Less than six weeks.	11	2.3 percent, the Burch at 2.8 percent and the
12	A. Yes.	12	retropubic at 3.6 percent?
13	Q. And 12 percent for pubovaginal slings?	13	A. Yes.
14	A. Yes.	14	You didn't want to discuss urethral
15	Q. 17 percent for the Burch?	15	perforation?
16	A. Yes.	16	Q. Sure. Urethral perforation, mini-sling,
17	Q. And they also looked at retention	17	they report 2.7 percent?
18	lasting longer than six weeks postoperatively,	18	A. Yes.
19	correct?	19	Q. And would you say that that is an
20	A. Yes.	20	accurate number?
21	Q. And for the mini-sling they reported 3.3	21	A. That was again described in the Cochrane
22	percent incidence rate	22	analysis in 2014 that there was a higher bladder
23	A. Yes.	23	and urethral risk associated with the mini-sling.
24	Q which would be lower than the	24	Q. And here they are showing that that's
	Page 199		Page 201
1	Page 199	1	Page 201 based on one study evaluating 37 patients, and out
1 2	pubovaginal sling at 7.5 percent and the Burch at	1 2	based on one study evaluating 37 patients, and out
2	pubovaginal sling at 7.5 percent and the Burch at 7.6 percent?	2	based on one study evaluating 37 patients, and out of those, one patient had urethral perforation?
2 3	pubovaginal sling at 7.5 percent and the Burch at 7.6 percent? A. Yes, but zero percent of those patients	2	based on one study evaluating 37 patients, and out of those, one patient had urethral perforation? A. That's what they described.
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	Page 202		Page 204
1	A. What we have discussed earlier and	1	Q. And what this study shows is at one-year
2	what's in my report.	2	followup, 1,334 women were studied?
3	Q. These authors go on to state in this SGS	3	A. Not at one-year followup, no.
4	meta-analysis that dyspareunia is rare with any	4	Q. What are you basing that on?
5	type of sling but is somewhat more common with a	5	A. On table I think it's Table 1 or
6	mini-sling at 0.99 percent than either a retropubic	6	Graph 1, where you have the consort analysis of the
7	at less than .001 percent or a obturator at 0.16	7	data, we see that only out of the 677 Secur, the
8	percent, correct?	8	469 TVT and the 252 TVT-O in the study, for Secur
9	A. That's what they describe.	9	45 withdrew their consent; 21 of the TVT withdrew
10	Q. And do you have any reason to dispute	10	their consent; 44 withdrew their consent for the
11	the findings that the authors concluded in this	11	TVT-O.
12	meta-analysis regarding dyspareunia being there?	12	There were 111 lost to followup for TVT
13	A. Specifically for TVT Secur?	13	Secur, 92 for TVT and 68 for TVT-O.
14	Q. Yes.	14	Contraction stress test for TVT Secur
15	A. Yes, the information that we have	15	was slightly higher 50 percent excuse me. Cough
16	discussed earlier.	16	stress tests were obtained in slightly above 50
17	Q. And if you look on 1.e18, the top left	17	percent of patients at 347 for Secur, 187 for TVT,
18	paragraph, am I correct that the authors of this	18	so it's less than 50 percent and also less than 50
19	meta-analysis determined that the TVT Secur was the	19	percent of one-tenth of TVT-O.
20	most widely studied mini-sling?	20	Q. And these results show that there was
21	A. On e18?	21	about an 84.2 percent objective cure rate for TVT
22	Q. Yes.	22	Secur?
23	A. Where are you looking?	23	A. With only 50 percent of patients being
24	Q. "It should be noted that this is the	24	followed up with a cough stress test at 12 months.
24	`	24	<u> </u>
	Page 203		
			Page 205
1	most widely studied mini-sling," and TVT Secur is	1	Q. With that caveat, based on the patients
2	most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that?	2	Q. With that caveat, based on the patients that they were able to follow up, these authors
2	most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that? A. Yes.	2	Q. With that caveat, based on the patients that they were able to follow up, these authors reported about a 84 percent cure rate for TVT
2 3 4	most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that? A. Yes. Q. Is that consistent with your review of	2 3 4	Q. With that caveat, based on the patients that they were able to follow up, these authors reported about a 84 percent cure rate for TVT Secur?
2 3 4 5	most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that? A. Yes. Q. Is that consistent with your review of the literature?	2 3 4 5	Q. With that caveat, based on the patients that they were able to follow up, these authors reported about a 84 percent cure rate for TVT Secur? A. With a 50 percent lost to followup, yes,
2 3 4 5 6	most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that? A. Yes. Q. Is that consistent with your review of the literature? A. Yes.	2 3 4 5 6	Q. With that caveat, based on the patients that they were able to follow up, these authors reported about a 84 percent cure rate for TVT Secur? A. With a 50 percent lost to followup, yes, that's what they report.
2 3 4 5 6 7	most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that? A. Yes. Q. Is that consistent with your review of the literature? A. Yes. Q. You can put that away. Now if you will	2 3 4 5 6 7	Q. With that caveat, based on the patients that they were able to follow up, these authors reported about a 84 percent cure rate for TVT Secur? A. With a 50 percent lost to followup, yes, that's what they report. Q. And these authors concluded that the TVT
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that? A. Yes. Q. Is that consistent with your review of the literature? A. Yes. Q. You can put that away. Now if you will look at Exhibit 17. Do you recognize this study? A. Yes. Q. And this is a study done by the lead author Tincello? A. Yes. Q. And it's the TVT Worldwide Observational Registry, correct? A. Yes. Q. And this is a study that you have on your reliance list? A. Correct. Q. You would consider this study to be authoritative and reliable? A. Correct. Q. And surgeons in your field would rely on	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. With that caveat, based on the patients that they were able to follow up, these authors reported about a 84 percent cure rate for TVT Secur? A. With a 50 percent lost to followup, yes, that's what they report. Q. And these authors concluded that the TVT Secur cohort had the shortest operative time, the lowest proportion of women who required an overnight stay and the most women who underwent surgery under local anesthesia. The median time did I read that correctly? A. Yes. Q. They go on to state the median time to return to employment, housework, sex life and hobbies was most rapid for Secur, correct? A. For the 50 percent of women that returned for followup, yes. Q. You agree that it would be a benefit to patients to be able to return to employment, housework, their sex lives and hobbies faster? A. We discussed the economic interest of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	most widely studied mini-sling," and TVT Secur is referenced on the previous page. Do you see that? A. Yes. Q. Is that consistent with your review of the literature? A. Yes. Q. You can put that away. Now if you will look at Exhibit 17. Do you recognize this study? A. Yes. Q. And this is a study done by the lead author Tincello? A. Yes. Q. And it's the TVT Worldwide Observational Registry, correct? A. Yes. Q. And this is a study that you have on your reliance list? A. Correct. Q. You would consider this study to be authoritative and reliable? A. Correct.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. With that caveat, based on the patients that they were able to follow up, these authors reported about a 84 percent cure rate for TVT Secur? A. With a 50 percent lost to followup, yes, that's what they report. Q. And these authors concluded that the TVT Secur cohort had the shortest operative time, the lowest proportion of women who required an overnight stay and the most women who underwent surgery under local anesthesia. The median time did I read that correctly? A. Yes. Q. They go on to state the median time to return to employment, housework, sex life and hobbies was most rapid for Secur, correct? A. For the 50 percent of women that returned for followup, yes. Q. You agree that it would be a benefit to patients to be able to return to employment, housework, their sex lives and hobbies faster?

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	Page 206		Page 208
1	A. That I there is no economic benefit	1	here, correct?
2	for returning to sex life, and I am not sure that	2	A. That's what these authors concluded.
3	my wife would agree that returning to housework is	3	Q. And for dyspareunia they have zero
4	an advantage.	4	percent for TVT Secur, correct?
5	Q. If you look	5	A. That's what they describe.
6	MR. WALDENBERGER: Did you want to	6	Q. If you look under the discussion
7	strike that last part?	7	sections, the authors indicate a major advantage of
8	Q. Page 2313, the paragraph on the right,	8	Secur appear to be its potential suitability for an
9	it states, starting in the middle of the sentence,	9	in-office based procedure rather than surgery
10	"low surgeon experience with fewer than 50	10	requiring formal day case hospitalization due to
11	procedures was associated with a lower likelihood	11	the safety profile, correct?
12	of success than surgeon experience with 50 to 99	12	MR. WALDENBERGER: "Correct" meaning
13	procedures," correct?	13	you read it right?
14	A. That's what they state.	14	MR. ROSENBLATT: Yes.
15	Q. And so what that suggests is that	15	MR. WALDENBERGER: Do you see where he
16	surgeons with more experience and higher volume	16	read?
17	have better success rates, correct, at least in	17	A. I'm going back to look at their methods
18	this study?	18	and seeing the number of patients
19	A. And that is what is described in my	19	Q. Did I read that correctly, Doctor?
20	report as one of the defects of the design of the	20	A. Yes, you did, but they do not describe
21	TVT Secur.	21	in their methods that any of the women actually had
22	Q. But you would agree with me that at	22	the procedure done in the office, so it is
23	least in this study, increased surgeon experience	23	difficult for me to agree with the statement that
24	and volume was attributed to better success rates?	24	it could be done in the office if they didn't even
	Page 207		· · · · · · · · · · · · · · · · · · ·
			Dage 209
1		1	Page 209
1 2	A. As described in my report, that is a	1 2	study it being done in the office.
2	A. As described in my report, that is a defect of the TVT Secur.	2	study it being done in the office. Q. And that's a study that was on your
2	A. As described in my report, that is a defect of the TVT Secur. Q. If you look at Table 2, which lists the	2	study it being done in the office. Q. And that's a study that was on your reliance list?
2 3 4	A. As described in my report, that is a defect of the TVT Secur. Q. If you look at Table 2, which lists the complications, it says bleeding greater than 200	2 3 4	study it being done in the office. Q. And that's a study that was on your reliance list? A. Correct.
2 3 4 5	A. As described in my report, that is a defect of the TVT Secur. Q. If you look at Table 2, which lists the complications, it says bleeding greater than 200 milliliters, and for TVT Secur, they report 0.7	2 3 4 5	study it being done in the office. Q. And that's a study that was on your reliance list? A. Correct. Q. And if you would look at Exhibit 18. Do
2 3 4 5 6	A. As described in my report, that is a defect of the TVT Secur. Q. If you look at Table 2, which lists the complications, it says bleeding greater than 200 milliliters, and for TVT Secur, they report 0.7 percent?	2 3 4 5 6	study it being done in the office. Q. And that's a study that was on your reliance list? A. Correct. Q. And if you would look at Exhibit 18. Do you recognize this study?
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2 3 4 5 6 7 8	A. As described in my report, that is a defect of the TVT Secur. Q. If you look at Table 2, which lists the complications, it says bleeding greater than 200 milliliters, and for TVT Secur, they report 0.7 percent? A. Correct. Q. And for postoperative complications	2 3 4 5 6 7 8	study it being done in the office. Q. And that's a study that was on your reliance list? A. Correct. Q. And if you would look at Exhibit 18. Do you recognize this study? A. Yes. Q. This is a study by Walsh, which looks at
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2 3 4 5 6 7 8 9	A. As described in my report, that is a defect of the TVT Secur. Q. If you look at Table 2, which lists the complications, it says bleeding greater than 200 milliliters, and for TVT Secur, they report 0.7 percent? A. Correct. Q. And for postoperative complications there is sling erosion. Do you see that? A. Correct.	2 3 4 5 6 7 8 9	study it being done in the office. Q. And that's a study that was on your reliance list? A. Correct. Q. And if you would look at Exhibit 18. Do you recognize this study? A. Yes. Q. This is a study by Walsh, which looks at a systematic review of TVT Secur procedures at 12 months in 1,178 women?
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2 3 4 5 6 7 8 9 10 11 12 13 14	A. As described in my report, that is a defect of the TVT Secur. Q. If you look at Table 2, which lists the complications, it says bleeding greater than 200 milliliters, and for TVT Secur, they report 0.7 percent? A. Correct. Q. And for postoperative complications there is sling erosion. Do you see that? A. Correct. Q. And if you go across, the numbers are 1.5 percent for TVT, 0.4 percent for TVT-O and 1.2 percent for TVT Secur. Do you see that? A. Yes, but you can't what they are	2 3 4 5 6 7 8 9 10 11 12 13 14	study it being done in the office. Q. And that's a study that was on your reliance list? A. Correct. Q. And if you would look at Exhibit 18. Do you recognize this study? A. Yes. Q. This is a study by Walsh, which looks at a systematic review of TVT Secur procedures at 12 months in 1,178 women? A. Yes. Q. And this would be reliable and authoritative? A. As far as data in 2011, yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. As described in my report, that is a defect of the TVT Secur. Q. If you look at Table 2, which lists the complications, it says bleeding greater than 200 milliliters, and for TVT Secur, they report 0.7 percent? A. Correct. Q. And for postoperative complications there is sling erosion. Do you see that? A. Correct. Q. And if you go across, the numbers are 1.5 percent for TVT, 0.4 percent for TVT-O and 1.2 percent for TVT Secur. Do you see that? A. Yes, but you can't what they are basing those percentages on is the total number of patients, not the total number of patients that came back at 12 months, because you don't know with the 50 percent lost to followup whether or not they had a long-term postoperative complication like sling erosion, groin pain, voiding dysfunction, mixed incontinence, abdominal pain, dyspareunia.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	study it being done in the office. Q. And that's a study that was on your reliance list? A. Correct. Q. And if you would look at Exhibit 18. Do you recognize this study? A. Yes. Q. This is a study by Walsh, which looks at a systematic review of TVT Secur procedures at 12 months in 1,178 women? A. Yes. Q. And this would be reliable and authoritative? A. As far as data in 2011, yes. Q. And surgeons in your field would rely on such studies? A. Yes. Q. And again, a systematic review would be higher on the pyramid of evidence-based medicine? A. Yes. Q. And these authors

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	Page 210		Page 212
1	Q. And these authors indicated that there	1	A. That's what they state.
2	was a 2.4 percent incidence of mesh exposure in the	2	Q. I hand you what's been marked as Exhibit
3	first year after a TVT Secur?	3	19. Do you recognize what I have just handed you?
4	A. That's what they describe.	4	A. Yes.
5	Q. These authors also describe a 1 percent	5	Q. And Exhibit 19 is the TVT Secur
6	dyspareunia rate, correct?	6	European feedback from May 15th, 2007?
7	A. That's what they describe.	7	A. Yes.
8	Q. And the authors also describe a 0.8	8	Q. And if you could, turn to this page that
9	percent rate for returning to the theater for	9	states, "Paris European Expert Meeting: Results
10	complications?	10	from Early Experience."
11	A. That is what they describe.	11	A. Yes.
12	Q. And these authors conclude that the cure	12	Q. And what this shows is a number of
13	rate, both objective and subjective cure, was 76	13	physicians here along with their respective
14	percent?	14	countries, correct?
15	A. That is what they describe.	15	A. Yes.
16	Q. And they describe that as being similar	16	Q. It also shows the number of patients who
17	to more established midurethral slings?	17	they have implanted a TVT Secur in, correct?
18	A. That's what they state.	18	A. Yes.
19	Q. If you would, turn to Page 655, Table 4,	19	Q. And to the right of that they list the
20	which relates to postoperative complications. You	20	dry rates or the cure rates from their earlier
21	see here there are 11 studies listed there?	21	experience with the TVT Secur, correct?
22	A. Yes.	22	A. Yes.
23	Q. And those are all studies evaluating	23	Q. What this shows is at least these
24	patients who had a TVT Secur?	24	surgeons had cure rates with TVT Secur anywhere
	Page 211		Page 213
1	A. Correct.	1	from 87 percent to 100 percent, correct?
2	Q. And in the next column over they list	2	A. On Page 1, on the first page, and then
3	out the mesh exposure rates for all the patients	3	the second page it goes down to 50 percent and up
4	who were followed up in those studies?	4	to 77 percent.
5	A. Correct.	5	Q. We will get there, but am I correct
6	Q. And that's where we get the total 2.4	6	
7	percent from, correct?		that
/	percent from, correct.	7	that A. Yes.
8	A. Correct.	7 8	
	-		A. Yes.
8	A. Correct.	8	A. Yes.Q. And on the next page we see the cure
8 9	A. Correct. Q. And if you look towards the right of the	8 9	A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent?
8 9 10	A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we	8 9 10	A. Yes.Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent?A. Correct.
8 9 10 11	A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct?	8 9 10 11	 A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent? A. Correct. Q. And this would suggest that there is a
8 9 10 11 12	 A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct? A. Correct. Q. And under the first paragraph of the discussion section the authors indicate "Synthetic 	8 9 10 11 12 13	 A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent? A. Correct. Q. And this would suggest that there is a learning curve with the TVT Secur that affects cure rates, correct? A. As I described in my report, that is a
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8 9 10 11 12 13 14 15	A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct? A. Correct. Q. And under the first paragraph of the discussion section the authors indicate "Synthetic midurethral slings are now considered to be the gold standard surgical treatment for women with SUI	8 9 10 11 12 13 14 15	 A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent? A. Correct. Q. And this would suggest that there is a learning curve with the TVT Secur that affects cure rates, correct? A. As I described in my report, that is a defect associated with the device. Q. But you would agree with that
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8 9 10 11 12 13 14 15 16 17	A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct? A. Correct. Q. And under the first paragraph of the discussion section the authors indicate "Synthetic midurethral slings are now considered to be the gold standard surgical treatment for women with SUI and have become the benchmark against which new therapeutic interventions must be assessed."	8 9 10 11 12 13 14 15 16 17	 A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent? A. Correct. Q. And this would suggest that there is a learning curve with the TVT Secur that affects cure rates, correct? A. As I described in my report, that is a defect associated with the device. Q. But you would agree with that proposition? A. Yes. That it is a defect associated
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8 9 10 11 12 13 14 15 16 17 18 19 20	A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct? A. Correct. Q. And under the first paragraph of the discussion section the authors indicate "Synthetic midurethral slings are now considered to be the gold standard surgical treatment for women with SUI and have become the benchmark against which new therapeutic interventions must be assessed." Did I read that correctly? A. You read that correctly.	8 9 10 11 12 13 14 15 16 17 18 19 20	 A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent? A. Correct. Q. And this would suggest that there is a learning curve with the TVT Secur that affects cure rates, correct? A. As I described in my report, that is a defect associated with the device. Q. But you would agree with that proposition? A. Yes. That it is a defect associated with the device, yes. Q. Okay. You can put that away. I handed
8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct? A. Correct. Q. And under the first paragraph of the discussion section the authors indicate "Synthetic midurethral slings are now considered to be the gold standard surgical treatment for women with SUI and have become the benchmark against which new therapeutic interventions must be assessed." Did I read that correctly? A. You read that correctly. Q. And again, what these authors concluded	8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent? A. Correct. Q. And this would suggest that there is a learning curve with the TVT Secur that affects cure rates, correct? A. As I described in my report, that is a defect associated with the device. Q. But you would agree with that proposition? A. Yes. That it is a defect associated with the device, yes. Q. Okay. You can put that away. I handed you what's been marked as Exhibit 20.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct? A. Correct. Q. And under the first paragraph of the discussion section the authors indicate "Synthetic midurethral slings are now considered to be the gold standard surgical treatment for women with SUI and have become the benchmark against which new therapeutic interventions must be assessed." Did I read that correctly? A. You read that correctly. Q. And again, what these authors concluded was that success rates and complication rates for	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent? A. Correct. Q. And this would suggest that there is a learning curve with the TVT Secur that affects cure rates, correct? A. As I described in my report, that is a defect associated with the device. Q. But you would agree with that proposition? A. Yes. That it is a defect associated with the device, yes. Q. Okay. You can put that away. I handed you what's been marked as Exhibit 20. Put this in that bottom portion there.
8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Correct. Q. And if you look towards the right of the table under pain and dyspareunia, that's where we get the 1 percent from, correct? A. Correct. Q. And under the first paragraph of the discussion section the authors indicate "Synthetic midurethral slings are now considered to be the gold standard surgical treatment for women with SUI and have become the benchmark against which new therapeutic interventions must be assessed." Did I read that correctly? A. You read that correctly. Q. And again, what these authors concluded	8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. Yes. Q. And on the next page we see the cure rates from anywhere from 50 percent to 77 percent? A. Correct. Q. And this would suggest that there is a learning curve with the TVT Secur that affects cure rates, correct? A. As I described in my report, that is a defect associated with the device. Q. But you would agree with that proposition? A. Yes. That it is a defect associated with the device, yes. Q. Okay. You can put that away. I handed you what's been marked as Exhibit 20.

54 (Pages 210 to 213)

Page 216 Page 214 1 Yes. 1 cure rate at that time increased to 84 percent, 2 Q. And is this the TVT Secur Quality Board 2 3 3 presentation? A. That's what this states. 4 4 Q. Now, I understand you are critical of A. Yes. 5 5 Q. And if you look on Page 2, what Ethicon the learning curve and some of the difficulties 6 б realized was that the potential root cause of lower around the surgical technique, but as I understand 7 efficacy rates in Germany was attributed to surgeon 7 your opinions, you are critical of the failure 8 training, correct? 8 rates based on -- that are attributable to 9 9 A. They call it proctor training. technique as opposed to the mesh, correct? 10 10 MR. WALDENBERGER: Objection to the Q. And based on your review of the 11 11 testimony and documents regarding TVT Secur, is it form, vague; I think mischaracterizes 12 your understanding that the experiences in 12 testimony. You can answer. 13 Australia and Germany were not consistent with the 13 A. The stiff laser-cut, heavyweight, 14 rest of the world and the United States? 14 small-pore mesh increases the risk of poor smooth 15 15 muscle contractility, which would explain the A. No. That it was not consistent. I 16 16 increased failure rate along with the difficulty in mean, it was consistent with what was seen in other 17 17 getting the Ethisorb fleece in the appropriate countries too, not just in Germany and Australia. 18 Q. So if you go to Page 4. I'm sorry. 18 position and dislodgement of the Ethisorb upon 19 Go to Page 9. It describes the German 19 removal of the inserter. 20 experience. It states that there was a spike in 20 Q. If a patient who had a TVT Secur had a 21 post-procedural incontinence complaints in February 21 mesh exposure, what is your differential diagnosis 22 of 2007 and investigation determined that the root 22 to determine what the mechanism or the cause of the 23 23 cause was preceptor-based training which had mesh exposure was? 24 variable results? 24 A. What is on my differential? Page 215 Page 217 1 1 A. That's what they state. O. Yes. 2 Q. If you go to Page 11, what this slide 2 MR. WALDENBERGER: Assuming what 3 3 indicates is Dr. Lucente's cure rates over time product they had? 4 4 MR. ROSENBLATT: TVT Secur. evaluating his first 25 patients, his first 77 5 5 patients, his first 108 patients, and then it looks Number one, the stiff mesh. Number two. 6 at his last 25 patients, correct? 6 tissue dragging from a small incision that is not 7 7 A. That's what this states. deep enough. The sharp edges of the introducer 8 8 that is pulling through tissue. Mesh contraction, Q. And what this shows is initially 9 Dr. Lucente's cure rates were around 60 percent in 9 degradation, chronic foreign body reaction, chronic 10 his first 25 patients, correct? 10 inflammation. 11 11 MR. WALDENBERGER: Slow down. A. Yes. 12 Q. And then as he gained more experience 12 MR. ROSENBLATT: I know it's exciting. 13 13 with the TVT Secur, when he looked at the first 77 A. And all the other things I've described 14 patients his success rate increased to 68.8 14 in my report. 15 percent? 15 Q. Are you able to attribute a specific 16 16 percentage of mesh exposures that are caused due to A. That's what this states. 17 Q. And as Dr. Lucente gained even more 17 the stiff mesh? 18 experience and familiarity with the technique of 18 A. A specific percentage? 19 TVT Secur, when looking at 108 patients, it shows 19 20 that his cure rates jumped up to 72.2 percent, 20 A. I think all of the things I described 21 21 correct? contribute to mesh exposure. 22 A. It had increased to 72.2 percent, yes. 22 Q. So there is no way for you to break out 23 Q. And if you just look back at the most 23 whether a mesh exposure was caused by the stiff 24 24 recent or the last 25 patients at this time, his mesh, the tissue dragging, the sharp edges, the

55 (Pages 214 to 217)

1 2	Page 218		Page 220
2	contraction or any other factor?	1	behind?
	MR. WALDENBERGER: This hypothetical	2	A. That's what this slide states.
3	patient we are talking about?	3	Q. And if you look at the next slide,
4	MR. ROSENBLATT: In this hypothetical	4	that's showing a TVT Secur in someone's hand,
5	patient.	5	correct?
6	MR. WALDENBERGER: Who he has never	6	A. Correct.
7	seen.	7	Q. And you would agree with me that it is
8	A. In a hypothetical patient, without	8	considerably smaller than the full-length slings,
9	knowing the specifics of the patient's surgical	9	correct?
10	course, postoperative course and other specifics	10	A. Correct.
11	about the patient, I would not be able to opine	11	Q. And if you turn to the next slide, it
12	about which of the mechanisms was more likely the	12	discusses how the TVT Secur is only eight
13	cause, which of the defects of the product were	13	centimeters long
14	more likely the cause of the mechanism of the	14	A. Correct.
15	injury that she sustained.	15	Q and how there are no exit points?
16	MR. ROSENBLATT: Would you mark that.	16	A. That's what they state.
17	(Rosenzweig Exhibit 21 was marked	17	Q. Now, if you will turn to the
18	for identification as of 2/4/16.)	18	third-to-the-last page, and this is a snapshot or a
19	BY MR. ROSENBLATT:	19	table of the TVT Secur abstracts from the IUGA 2007
20	Q. Doctor, I have handed you what's been	20	meeting?
21	marked as Exhibit 21, and the Bates stamp on this	21	A. Yes.
22	is ETH.MESH.00369999.	22	Q. And so these would have been abstracts
23	A. Yes.	23	that would have been published in the medical
24	Q. Doctor, do you understand this to be a	24	literature as well as presented at this
	Page 219		Page 221
1	professional education slide deck for TVT Secur?	1	international conference?
2	A. Yes.	2	A. Yes.
3	Q. And if you could, turn to the pages		
		3	Q. And what this study shows is that when
4	aren't numbered, but at the top it states "Surgeon	3 4	
	aren't numbered, but at the top it states "Surgeon feedback for third generation." Are you there?		Q. And what this study shows is that when
4	•	4	Q. And what this study shows is that when you look at these seven studies evaluating 410
4 5	feedback for third generation." Are you there?	4 5	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure
4 5 6	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle.	4 5 6	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent?
4 5 6 7	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in,	4 5 6 7	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what
4 5 6 7 8	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page.	4 5 6 7 8	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state.
4 5 6 7 8 9	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page. MR. WALDENBERGER: Got it.	4 5 6 7 8 9	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state. Q. Put that away. This is 22.
4 5 6 7 8 9	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page. MR. WALDENBERGER: Got it. THE WITNESS: Okay.	4 5 6 7 8 9	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state. Q. Put that away. This is 22. (Rosenzweig Exhibit 22 was marked
4 5 6 7 8 9 10	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page. MR. WALDENBERGER: Got it. THE WITNESS: Okay. BY MR. ROSENBLATT: Q. And it states, "Surgeon feedback before third generation. Wanted simpler and less invasive	4 5 6 7 8 9 10	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state. Q. Put that away. This is 22. (Rosenzweig Exhibit 22 was marked for identification as of 2/4/16.)
4 5 6 7 8 9 10 11	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page. MR. WALDENBERGER: Got it. THE WITNESS: Okay. BY MR. ROSENBLATT: Q. And it states, "Surgeon feedback before	4 5 6 7 8 9 10 11	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state. Q. Put that away. This is 22. (Rosenzweig Exhibit 22 was marked for identification as of 2/4/16.) BY MR. ROSENBLATT:
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4 5 6 7 8 9 10 11 12 13 14 15	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page. MR. WALDENBERGER: Got it. THE WITNESS: Okay. BY MR. ROSENBLATT: Q. And it states, "Surgeon feedback before third generation. Wanted simpler and less invasive techniques to reduce potential complications." Correct? A. That's what they state. Q. And they list bullet points there to	4 5 6 7 8 9 10 11 12 13 14 15	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state. Q. Put that away. This is 22. (Rosenzweig Exhibit 22 was marked for identification as of 2/4/16.) BY MR. ROSENBLATT: Q. Doctor, do you recognize what I've handed you that has been marked as Exhibit 22? A. Yes. Q. And this is a professional education slide deck regarding TVT Secur, Bates number
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page. MR. WALDENBERGER: Got it. THE WITNESS: Okay. BY MR. ROSENBLATT: Q. And it states, "Surgeon feedback before third generation. Wanted simpler and less invasive techniques to reduce potential complications." Correct? A. That's what they state. Q. And they list bullet points there to maximize safety, minimize passage or minimal	4 5 6 7 8 9 10 11 12 13 14 15 16	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state. Q. Put that away. This is 22. (Rosenzweig Exhibit 22 was marked for identification as of 2/4/16.) BY MR. ROSENBLATT: Q. Doctor, do you recognize what I've handed you that has been marked as Exhibit 22? A. Yes. Q. And this is a professional education slide deck regarding TVT Secur, Bates number FMESH00308094. This is from July of 2006.
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page. MR. WALDENBERGER: Got it. THE WITNESS: Okay. BY MR. ROSENBLATT: Q. And it states, "Surgeon feedback before third generation. Wanted simpler and less invasive techniques to reduce potential complications." Correct? A. That's what they state. Q. And they list bullet points there to maximize safety, minimize passage or minimal passage through tissues and less material left behind in the patient, correct? A. That's what they state. Q. And you agree based on the slide that	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state. Q. Put that away. This is 22. (Rosenzweig Exhibit 22 was marked for identification as of 2/4/16.) BY MR. ROSENBLATT: Q. Doctor, do you recognize what I've handed you that has been marked as Exhibit 22? A. Yes. Q. And this is a professional education slide deck regarding TVT Secur, Bates number FMESH00308094. This is from July of 2006. A. Yes. Q. And I would like you to turn towards the end, about six or seven pages from the end, at the top, "Gynecare TVT Secur System Early Clinical
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	feedback for third generation." Are you there? MR. WALDENBERGER: Past the middle. MR. ROSENBLATT: About six pages in, seventh page. MR. WALDENBERGER: Got it. THE WITNESS: Okay. BY MR. ROSENBLATT: Q. And it states, "Surgeon feedback before third generation. Wanted simpler and less invasive techniques to reduce potential complications." Correct? A. That's what they state. Q. And they list bullet points there to maximize safety, minimize passage or minimal passage through tissues and less material left behind in the patient, correct? A. That's what they state.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And what this study shows is that when you look at these seven studies evaluating 410 patients, that there was an average subjective cure rate of 85.4 percent? A. At six weeks, 6.6 weeks, that's what they state. Q. Put that away. This is 22. (Rosenzweig Exhibit 22 was marked for identification as of 2/4/16.) BY MR. ROSENBLATT: Q. Doctor, do you recognize what I've handed you that has been marked as Exhibit 22? A. Yes. Q. And this is a professional education slide deck regarding TVT Secur, Bates number FMESH00308094. This is from July of 2006. A. Yes. Q. And I would like you to turn towards the end, about six or seven pages from the end, at the

56 (Pages 218 to 221)

Page 222 Page 224 1 Q. And what this is discussing are just 1 from what doctors around the country, including 2 some, I guess, lessons learned or some tips and 2 Dr. Farnsworth, said, that tension-free is a 3 3 tricks in this professional education slide deck, misnomer. It was never tension-free. Dr. Arnaud 4 correct? 4 and Hinoul had that in one of his presentations 5 5 A. Yes. that we were never tension-free and we will never 6 6 Q. And if you look at the bottom it says, be tension-free. 7 "Do not retract or pull on mesh while removing 7 So, this was -- the TVT Secur was 8 inserter. Do not use the Babcock technique," 8 specifically placed with greater tension than, 9 9 correct? quote-unquote, the tension-free, which is a 10 10 misnomer because there is no way to place these A. Correct. 11 11 Q. And the Babcock technique would tension-free. 12 essentially be when you put a Babcock or sometimes 12 Q. And you will agree that surgeons who 13 another surgical instrument such as a helical 13 became familiar and experienced with the tensioning 14 passer in between the urethra and the mesh, 14 of the TVT Secur had good results? 15 15 MR. WALDENBERGER: Objection to form correct? 16 16 You can answer. It's vague. A. No. 17 17 A. With what? Q. Or you are clamping a little bit of the 18 mesh to prevent or to leave a little tension? 18 O. With TVT Secur. 19 A. The Babcock technique was specifically 19 MR. WALDENBERGER: Objection to the 20 taught by Dr. DeLaval for the obturator, TVT 20 extent that "results" is a vague term that you 21 obturator technique. 21 are not relating it to a particular thing. 22 Q. And the intent of the Babcock technique 22 You can answer if you understand. was to make sure that the mesh wasn't tensioned too 23 MR. ROSENBLATT: I will rephrase. 23 24 tight, correct? 24 Page 223 Page 225 1 A. The observation was that it was much BY MR. ROSENBLATT: 2 more difficult to remove the sleeves with the TVT 2 Q. You will agree with me that there were 3 3 obturator and therefore, you needed to hold a surgeons who were able to refine the technique for 4 4 TVT Secur, correct? 2-millimeter knuckle of sling in a Babcock when 5 removing the sheath to avoid putting too much 5 A. There were surgeons that reported a higher success rate than other surgeons. б tension on the urethra. 6 7 7 Q. And that's a technique that surgeons Q. And so at least for some surgeons who 8 employed over time to help facilitate a better mesh 8 were able to learn the nuances of the TVT Secur 9 placement, correct? 9 procedure, they had good results as far as high 10 A. Or the TVT obturator. 10 success rates and low complications in some 11 11 Q. And what this slide deck is relaying to patients, correct? 12 physicians is that the consequence of using the 12 MR. WALDENBERGER: Objection to form Babcock technique with the TVT Secur is that the 13 13 You can answer. mesh will be too loose, correct? 14 14 A. And there are other doctors who were 15 A. That's what they state. 15 taught the nuances that could not get a higher 16 Q. And it states the implant will not get 16 success rate and a lower complication rate. 17 tighter as with current TVT? 17 O. And I understand that. There were some 18 A. Meaning that the mesh contracts. 18 surgeons who were retrained and they still didn't 19 Q. And so, Doctor, would you agree that a 19 have great results, correct? 20 benefit of TVT Secur is that it was difficult to 20 A. Correct. 21 overtension or provide excessive tension? 21 Q. But on the contrary, there were surgeons 22 who were comfortable with the tensioning of the TVT A. No. As I describe in my report, one of 22 23 the other tips and tricks was to place this under, 23 Secur, correct? quote-unquote, more tension than the TVT. We know A. There are --24 24

57 (Pages 222 to 225)

	Page 226		Page 228
1	MR. WALDENBERGER: Objection to the	1	Doctor, I have got one that might
2	form. You can answer.	2	refresh your recollection, so
3	A. There were doctors that reported better	3	A. All right.
4	success rates.	4	Q. If you could look at what I've just
5	Q. And so at least for some doctors who	5	handed you that has been marked as Exhibit 23.
6	were comfortable with the TVT Secur and the	6	Have you seen this document before?
7	surgical technique, they had good patient results?	7	A. Yes.
8	A. There are doctors that reported better	8	Q. And this is the TVT Secur PQI07-041
9	surgical outcomes and higher success rates.	9	Quality Board followup, correct?
10	Q. And so for those doctors and those	10	A. Yes.
11	patients, TVT Secur was a good product for them?	11	Q. And this presentation is essentially an
12	MR. WALDENBERGER: Objection to the	12	analysis of the efficacy problems observed in
13	form. You can answer.	13	Australia and Germany, correct?
14	A. I cannot speak to the individual	14	A. It's the review of global complaints
15	patients.	15	looked at by region and country.
16	MR. WALDENBERGER: Or their	16	Q. And so, for example, if you look at
17	physicians.	17	Page 4 titled "Global Complaint Review," they look
18	THE WITNESS: Or their physicians.	18	at they do Pareto analyses and see that the top
19	MR. ROSENBLATT: Go to the witness.	19	global complaint is post-procedure incontinence?
20	MR. WALDENBERGER: That's the first	20	A. Correct.
21	time after 4 hours and 38 minutes.	21	Q. And post-procedure incontinence is
22	MR. ROSENBLATT: You get one. I will	22	essentially a problem with efficacy or the
23	tell you what. If you could give me five	23	procedure did not cure incontinence as it was
24	minutes just to make sure we don't have any	24	intended to do, correct?
		21	· · · · · · · · · · · · · · · · · · ·
	Page 227		
			Page 229
1	wrap-up questions and we will be out of your	1	A. Correct.
2	wrap-up questions and we will be out of your hair.	2	A. Correct.Q. And failure of a procedure is a
2 3	wrap-up questions and we will be out of your hair. MR. WALDENBERGER: Sure, go for it.	2	A. Correct.Q. And failure of a procedure is a recognized complication with any surgery intended
2 3 4	wrap-up questions and we will be out of your hair. MR. WALDENBERGER: Sure, go for it. MR. ROSENBLATT: Off the record.	2 3 4	A. Correct. Q. And failure of a procedure is a recognized complication with any surgery intended to treat stress urinary incontinence, correct?
2 3 4 5	wrap-up questions and we will be out of your hair. MR. WALDENBERGER: Sure, go for it. MR. ROSENBLATT: Off the record. (Recess taken, 2:28 - 2:35 p.m.)	2 3 4 5	 A. Correct. Q. And failure of a procedure is a recognized complication with any surgery intended to treat stress urinary incontinence, correct? A. It is, depending on what the rate of
2 3 4 5 6	wrap-up questions and we will be out of your hair. MR. WALDENBERGER: Sure, go for it. MR. ROSENBLATT: Off the record. (Recess taken, 2:28 - 2:35 p.m.) (Mr. Campbell left the deposition	2 3 4 5 6	 A. Correct. Q. And failure of a procedure is a recognized complication with any surgery intended to treat stress urinary incontinence, correct? A. It is, depending on what the rate of post-procedural incontinence is.
2 3 4 5 6 7	wrap-up questions and we will be out of your hair. MR. WALDENBERGER: Sure, go for it. MR. ROSENBLATT: Off the record. (Recess taken, 2:28 - 2:35 p.m.) (Mr. Campbell left the deposition proceedings.)	2 3 4 5 6 7	 A. Correct. Q. And failure of a procedure is a recognized complication with any surgery intended to treat stress urinary incontinence, correct? A. It is, depending on what the rate of post-procedural incontinence is. Q. And so in this presentation Ethicon is
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58 (Pages 226 to 229)

	Page 230		Page 232
1	line.	1	the Okulu study?
2	Q. And what are you basing that on?	2	A. Correct.
3	A. The fact that, as I described it during	3	Q. And you are not aware of any other
4	the Abbrevo trial, that Gynemesh PS is less stiff	4	studies evaluating Ultrapro as a sling in women?
5	than Gynemesh.	5	A. Not that I'm aware of.
6	Q. Any clinical studies that you are	6	Q. I want to go back to Page 7 of this
7	relying on?	7	slide deck, and again, this presentation is
8	A. No. That's based on internal documents	8	summarizing the results of the global complaint
9	from Ethicon.	9	review, and this slide shows ROW, which can we
10	Q. But as I understand it, you are not	10	agree urethra that stands for rest of the world?
11	offering the opinion in your expert report that	11	A. Yes.
12	Gynemesh PS is a safer alternative design, correct?	12	Q. So what this shows is that the
13	A. I am not offering Gynemesh PS as a safer	13	experiences with the rest of the world are not
14	alternative design.	14	similar to the efficacy and complaint rates in the
15	Q. And am I correct that the safer	15	United States, correct?
16	alternative design that you are suggesting in this	16	A. Correct.
17	case for TVT Secur is the Ultrapro mesh?	17	Q. And if you turn to Page 8, a global
18	A. Correct.	18	complaint review that Ethicon performed determined
19	Q. And that's based on the Okulu study?	19	that the German experience regarding efficacy and
20	A. That's one of the studies.	20	complaints was not similar to the experiences in
21	Q. What other clinical studies are you	21	the United States, correct?
22	relying on to support your opinion that Ultrapro	22	A. That's what they describe in this slide.
23	would be a safer mesh?	23	Q. And if you turn to Page 9, the analysis
24	A. The studies from the Moalli group that	24	determined that the Australian experience was not
	<u> </u>		<u> </u>
	Page 231		
			Page 233
1	look at the lighter weight, larger pore mesh.	1	similar to the efficacy rates and complaints in the
2	look at the lighter weight, larger pore mesh. Q. I'm sorry to cut you off. I'm talking	2	similar to the efficacy rates and complaints in the United States, correct?
2 3	look at the lighter weight, larger pore mesh. Q. I'm sorry to cut you off. I'm talking about clinical studies in women.	2	similar to the efficacy rates and complaints in the United States, correct? A. That's what this states.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	look at the lighter weight, larger pore mesh. Q. I'm sorry to cut you off. I'm talking about clinical studies in women. A. Specifically looking at a partially absorbable mesh? Q. Yes. A. And specifically compared to a non-partially absorbable mesh? Q. I don't care if it's comparing it to anything. I want to know what clinical studies using a partially absorbable mesh, i.e., Ultrapro, that you are relying on to support your opinion. A. There are I don't think that they are on this reliance list, but they might be. There are several studies that have looked at partially absorbable mesh and the efficacy and partially absorbable mesh and the benefit to a non-partially absorbable mesh. Q. But I'm correct that those are not on your reliance list here? I didn't see them. A. That I haven't looked at specifically	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	similar to the efficacy rates and complaints in the United States, correct? A. That's what this states. Q. And if you turn to Page 10, what they determined there was that the German and Australian experiences are not similar to the rest of the world and/or the United States, correct? A. If you lump the rest of the world together as they did in this slide or the United States, that's what they showed in this slide. Q. Do you have any reason to disagree with the findings on this page? A. On this page? Q. Yes. A. This is what this page shows. Q. My question was just a little bit different. Do you have any reason to disagree with the findings on this page? A. There are other internal documents that say that the German and Australian experience was not unique as compared to what other doctors were

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1 2	Page 234		Page 236
2	Q. And you don't recall which ones those	1	exceeded with TVT Secur, correct?
	would be?	2	MR. WALDENBERGER: Objection to the
3	A. I don't recall specifically right now	3	form. You can answer.
4	which documents they are.	4	A. This states physicians only,
5	Q. Do you recall if it was a formal	5	quote-unquote, complain when this rate exceeded.
6	analysis such as the presentation in front of you?	6	Q. We are done with that document.
7	A. If I recall, it was a discussion between	7	Doctor, are you critical of Ethicon for
8	medical directors.	8	continuing to improve their strike that.
9	Q. And if you turn to Page 14, what this	9	Are you critical of Ethicon for making
10	shows is the German and Australian experiences are,	10	attempts to improve their professional education
11	quote-unquote, different, correct?	11	materials even after TVT Secur was launched?
12	A. That's what this slide states.	12	A. In what respect?
13	Q. And it also states that they are	13	Q. Do you think it's a good thing that
14	different than the USA?	14	companies should try to continue to improve
15	A. That's what it states.	15	training and education materials?
16	Q. It states that they are different than	16	MR. WALDENBERGER: You are not talking
17	the rest of the world outside of the USA?	17	specifically regarding the TVT-S?
18	A. That's what this slide states.	18	MR. ROSENBLATT: Not right now; just
19	Q. Now, what's important is that next	19	in general.
20	bullet point, which states "Together the German"	20	MR. WALDENBERGER: You can answer
21	strike that. Paraphrasing here.	21	that.
22	This next bullet point essentially	22	A. Yes.
23	states that the German and Australian TVT Secur	23	Q. With respect to the TVT Secur, do you
24	sales were about 6.4 percent, but the complaints	24	agree that it was beneficial for Ethicon to
	Page 235		Page 237
1	from Germany and Australia accumulated to 91	1	recognize that there was a problem with efficacy in
2	percent of the total complaints regarding efficacy	2	certain locations and take steps necessary to
3	with TVT Secur?	3	improve the professional education?
4	A. That's what this slide states.	4	MR. WALDENBERGER: Objection to the
5	Q. And other than the internal e-mails that	5	form. You can answer.
6	you have seen discussing something contrary to	6	A. And what are you talking about as far as
	this, do you have any reason to dispute the	7	steps go? That's what I'm
7	findings on this page?		steps go: That's what Thi
7 8	maings on this page?	8	Q. Putting out additional professional
	A. That's what this slide states.	8 9	1 0
8		l .	Q. Putting out additional professional
8 9	A. That's what this slide states.	9	Q. Putting out additional professional education materials, making the steps clearer,
8 9 10	A. That's what this slide states.Q. And you are not able to point me to the	9 10	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various
8 9 10 11	A. That's what this slide states.Q. And you are not able to point me to the e-mails that would contradict the findings on this	9 10 11	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU.
8 9 10 11 12	A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you?	9 10 11 12	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks,
8 9 10 11 12 13	A. That's what this slide states.Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you?A. I don't have them at my fingertips, no.	9 10 11 12 13	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks?
8 9 10 11 12 13 14	 A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you? A. I don't have them at my fingertips, no. Q. And if you turn to Page 15, part of the 	9 10 11 12 13 14	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks? Q. Sure.
8 9 10 11 12 13 14 15	A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you? A. I don't have them at my fingertips, no. Q. And if you turn to Page 15, part of the conclusion of the internal global complaint review	9 10 11 12 13 14 15	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks? Q. Sure. A. I describe that in my report.
8 9 10 11 12 13 14 15 16	A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you? A. I don't have them at my fingertips, no. Q. And if you turn to Page 15, part of the conclusion of the internal global complaint review was that aside from the outliers of Australia and	9 10 11 12 13 14 15 16	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks? Q. Sure. A. I describe that in my report. Q. Right. My question is, are you critical
8 9 10 11 12 13 14 15 16	A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you? A. I don't have them at my fingertips, no. Q. And if you turn to Page 15, part of the conclusion of the internal global complaint review was that aside from the outliers of Australia and Germany, there were no safety signals, correct?	9 10 11 12 13 14 15 16	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks? Q. Sure. A. I describe that in my report. Q. Right. My question is, are you critical of Ethicon for continuing to try to improve the
8 9 10 11 12 13 14 15 16 17	A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you? A. I don't have them at my fingertips, no. Q. And if you turn to Page 15, part of the conclusion of the internal global complaint review was that aside from the outliers of Australia and Germany, there were no safety signals, correct? A. That's what this slide states.	9 10 11 12 13 14 15 16 17	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks? Q. Sure. A. I describe that in my report. Q. Right. My question is, are you critical of Ethicon for continuing to try to improve the professional education regarding the TVT Secur?
8 9 10 11 12 13 14 15 16 17 18	A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you? A. I don't have them at my fingertips, no. Q. And if you turn to Page 15, part of the conclusion of the internal global complaint review was that aside from the outliers of Australia and Germany, there were no safety signals, correct? A. That's what this slide states. Q. And it also states that the mean failure	9 10 11 12 13 14 15 16 17 18	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks? Q. Sure. A. I describe that in my report. Q. Right. My question is, are you critical of Ethicon for continuing to try to improve the professional education regarding the TVT Secur? A. If these are critical steps, they should
8 9 10 11 12 13 14 15 16 17 18 19 20	A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you? A. I don't have them at my fingertips, no. Q. And if you turn to Page 15, part of the conclusion of the internal global complaint review was that aside from the outliers of Australia and Germany, there were no safety signals, correct? A. That's what this slide states. Q. And it also states that the mean failure rate for any TVT was approximately 15 to 20 percent? A. That's what this slide states.	9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks? Q. Sure. A. I describe that in my report. Q. Right. My question is, are you critical of Ethicon for continuing to try to improve the professional education regarding the TVT Secur? A. If these are critical steps, they should have been placed in the instructions for use and
8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. That's what this slide states. Q. And you are not able to point me to the e-mails that would contradict the findings on this page right now, are you? A. I don't have them at my fingertips, no. Q. And if you turn to Page 15, part of the conclusion of the internal global complaint review was that aside from the outliers of Australia and Germany, there were no safety signals, correct? A. That's what this slide states. Q. And it also states that the mean failure rate for any TVT was approximately 15 to 20 percent?	9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Putting out additional professional education materials, making the steps clearer, coming out with key technique guides and various materials to supplement the IFU. A. So you are talking about cookbooks, pearls and tips and tricks? Q. Sure. A. I describe that in my report. Q. Right. My question is, are you critical of Ethicon for continuing to try to improve the professional education regarding the TVT Secur? A. If these are critical steps, they should have been placed in the instructions for use and the instructions for use should have been updated

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1	Page 238		Page 240
1 1	performing what is now the Burch, that procedure	1	A. Yes.
2	was done slightly differently, correct?	2	Q. Other than the studies that you
3	A. When I first started to perform the	3	mentioned a moment ago, are you aware of any other
4	procedure?	4	cadaver labs or testing that was done on TVT Secur
5	O. The MMK.	5	prior to launch?
6	A. When I first started to perform the	6	A. Specifically those were the three areas
7	Burch procedure?	7	that I saw of studies.
8	Q. Yes?	8	Q. Do you agree that a benefit of laser-cut
9	A. The same procedure that I do currently	9	mesh in particular with the TVT Secur is that it
10	have.	10	has less potential to cause retention than TVT or
11	Q. You haven't made any adjustments to your	11	TVT-O?
12	Burch procedure?	12	A. Can you repeat the question?
13	A. I've always done the Tanagho	13	Q. Yes. Do you agree that one of the
14	modification. Tanagho, T-a-n-a-g-h-o.	14	benefits of laser-cut mesh is that strike that.
15	Q. And you would agree with me that not all	15	Would you agree with me that one of the
16	surgeons who perform the Burch procedure do the	16	benefits of laser-cut mesh used in TVT Secur is
17	Tanagho modification?	17	that it has less potential to cause retention than
18	A. I can tell you what I do.	18	TVT or TVT-O?
19	Q. So you don't know how other surgeons	19	A. And am I assuming that the mesh used for
20	perform the Burch, correct?	20	the TVT or TVT-O is laser cut also?
21	A. I would say that when the Tanagho	21	Q. You tell me. Does that change your
22	modification was described, it was adopted as the,	22	answer?
23	you know, best way to perform the Burch procedure.	23	A. I'm not the one that's asking the
24	Q. And that was based on experience over	24	question.
1	Page 239	,	Page 241
1	time, correct?	1	O A
	A		Q. Assume that TVT and TVT-O are
2	A. Correct.	2	mechanically cut.
3	Q. And that was based on comparing	2	mechanically cut. A. Would the laser cut minimize the risk of
3 4	Q. And that was based on comparing complication and efficacy rates over time, correct?	2 3 4	mechanically cut. A. Would the laser cut minimize the risk of retention?
3 4 5	Q. And that was based on comparing complication and efficacy rates over time, correct?A. Correct.	2 3 4 5	mechanically cut. A. Would the laser cut minimize the risk of retention? Q. Yes.
3 4 5 6	Q. And that was based on comparing complication and efficacy rates over time, correct?A. Correct.Q. And after performing Burch procedure	2 3 4 5 6	mechanically cut. A. Would the laser cut minimize the risk of retention? Q. Yes. A. Compared to TVT and TVT retropubic, TVT
3 4 5 6 7	 Q. And that was based on comparing complication and efficacy rates over time, correct? A. Correct. Q. And after performing Burch procedure over time, some surgeons saw a benefit to 	2 3 4 5 6 7	mechanically cut. A. Would the laser cut minimize the risk of retention? Q. Yes. A. Compared to TVT and TVT retropubic, TVT and TVT-O?
3 4 5 6 7 8	 Q. And that was based on comparing complication and efficacy rates over time, correct? A. Correct. Q. And after performing Burch procedure over time, some surgeons saw a benefit to performing the Tanagho modification, correct? 	2 3 4 5 6 7 8	mechanically cut. A. Would the laser cut minimize the risk of retention? Q. Yes. A. Compared to TVT and TVT retropubic, TVT and TVT-O? Q. Yes.
3 4 5 6 7 8	 Q. And that was based on comparing complication and efficacy rates over time, correct? A. Correct. Q. And after performing Burch procedure over time, some surgeons saw a benefit to performing the Tanagho modification, correct? A. The Tanagho modification has benefits, 	2 3 4 5 6 7 8	mechanically cut. A. Would the laser cut minimize the risk of retention? Q. Yes. A. Compared to TVT and TVT retropubic, TVT and TVT-O? Q. Yes. A. We are comparing apples and oranges.
3 4 5 6 7 8 9	 Q. And that was based on comparing complication and efficacy rates over time, correct? A. Correct. Q. And after performing Burch procedure over time, some surgeons saw a benefit to performing the Tanagho modification, correct? A. The Tanagho modification has benefits, yes. 	2 3 4 5 6 7 8 9	mechanically cut. A. Would the laser cut minimize the risk of retention? Q. Yes. A. Compared to TVT and TVT retropubic, TVT and TVT-O? Q. Yes. A. We are comparing apples and oranges. MR. ROSENBLATT: Just give me one
3 4 5 6 7 8 9 10	 Q. And that was based on comparing complication and efficacy rates over time, correct? A. Correct. Q. And after performing Burch procedure over time, some surgeons saw a benefit to performing the Tanagho modification, correct? A. The Tanagho modification has benefits, yes. Q. Doctor, have you reviewed the entire 	2 3 4 5 6 7 8 9 10	mechanically cut. A. Would the laser cut minimize the risk of retention? Q. Yes. A. Compared to TVT and TVT retropubic, TVT and TVT-O? Q. Yes. A. We are comparing apples and oranges. MR. ROSENBLATT: Just give me one second. I will try to wrap up with this,
3 4 5 6 7 8 9 10 11	 Q. And that was based on comparing complication and efficacy rates over time, correct? A. Correct. Q. And after performing Burch procedure over time, some surgeons saw a benefit to performing the Tanagho modification, correct? A. The Tanagho modification has benefits, yes. Q. Doctor, have you reviewed the entire design history file for TVT Secur? 	2 3 4 5 6 7 8 9 10 11	mechanically cut. A. Would the laser cut minimize the risk of retention? Q. Yes. A. Compared to TVT and TVT retropubic, TVT and TVT-O? Q. Yes. A. We are comparing apples and oranges. MR. ROSENBLATT: Just give me one second. I will try to wrap up with this, Doctor.
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61 (Pages 238 to 241)

Page 242 Page 244 literature, their discussions with colleagues, 1 1 know, what all pelvic surgeons are exposed to, what 2 their experience at seminars, professional society 2 all pelvic surgeons read. 3 3 meetings and other education events? Obviously I have been exposed to and 4 MR. WALDENBERGER: You want to re-read 4 read things that are probably not available to the 5 5 that one? Is it compound? average pelvic surgeon, but based on what their 6 6 THE WITNESS: I mean -patient population is, their interest level, the 7 MR. ROSENBLATT: I'm trying to save 7 information they're exposed to, then yes. 8 8 some time, but I can break it down for you. Q. Would you agree that a reasonably 9 9 MR. WALDENBERGER: Why don't you break prudent pelvic floor surgeon performing 10 10 incontinence procedures would be aware of the risks it down. 11 BY MR. ROSENBLATT: 11 and complications associated with the Burch 12 Q. Doctor, would you agree that a 12 colposuspension procedure? 13 reasonably prudent pelvic floor surgeon would be 13 A. Again, depending on their level of 14 expected to make evidence-based decisions based on 14 training, their expertise, the patient population 15 their medical training? 15 that they see, their training, yes. 16 16 A. Yes. Q. And would that same answer apply to 17 Q. Based on their clinical experience? 17 synthetic midurethral slings? 18 Yes, in the hypothetical sense. 18 A. Well, there are a variety of aspects of 19 Q. Yes. 19 the synthetic midurethral slings that is intrinsic 20 2.0 A. Okay. to the procedure and to the material itself, and so 21 Q. Based on their review of published 21 I am not -- I do not think that the average medical literature? 22 22 physician would know all of the aspects of the A. That they have available, yes. 23 23 synthetic material itself, such as degradation, 24 Q. Based on their discussions with mentors 24 mesh contraction, the chronic foreign body reaction Page 243 Page 245 and colleagues? 1 and the implications of the chronic foreign body 1 2 A. Assuming that they are having 2 reaction, all the things that I described in my 3 3 discussions with mentors and colleagues, yes. report. 4 4 Q. And based on their experience at Q. What are you basing that on? 5 5 professional society meetings and seminars? A. What am I basing that on? 6 A. Depending on their availability to go to 6 Q. Yes. 7 7 professional meetings and seminars. A. Having spent five years intensively 8 8 Q. And based on their involvement in researching and reading and reviewing not only the 9 professional education, events or continuing 9 medical literature but internal documents, 10 medical education events? 10 testimony from medical experts at Ethicon. I have 11 11 A. Based on what medical seminars and been exposed to and have read and seen and probably 12 continuing medical education events that are 12 know more than the average physician just because 13 13 of the sheer volume of material that I have available to them. 14 14 Q. And you would agree that a reasonably reviewed. 15 prudent pelvic floor surgeon would be aware of the 15 Q. But you don't know what the average 16 potential risks associated with general surgery? 16 physician does or doesn't know, do you? 17 A. If they are a general surgeon. 17 MR. WALDENBERGER: Objection to form 18 Q. And you would agree that a reasonably 18 You can answer. 19 prudent pelvic floor surgeon would be aware of the 19 A. No, I do not. 20 potential risk associated with all pelvic floor 20 Q. Would you agree with me, Doctor, that 21 21 regardless of whether a synthetic midurethral sling surgeries? 22 is laser cut or mechanically cut, they can 22 A. It depends on again their level of 23 education, their level of experience. It's very 23 ultimately lead to the same complications? 24 difficult for me to say what all pelvic surgeons A. By different mechanisms, yes. 24

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	Page 246		Page 248
1	MR. ROSENBLATT: Nothing further at	1	INSTRUCTIONS TO WITNESS
2	this time.	2	n (STREETIGE STO WITH ESS
3	MR. WALDENBERGER: No questions.	3	Please read your deposition
4	MR. LUNDQUIST: None for the MDL	4	over carefully and make any necessary
5	either.	5	corrections. You should state the reason
6	THE REPORTER: Signature?	6	in the appropriate space on the errata
7	MR. WALDENBERGER: Read and sign,	7	sheet for any corrections that are made.
8	usual stips, read and sign.	8	After doing so, please sign
9	MR. ROSENBLATT: And my understanding	9	the errata sheet and date it. It will be
10	is that the de bene esse deposition will take	10	attached to your deposition.
11	place next Wednesday.	11	It is imperative that you
12	MR. WALDENBERGER: Correct.	12	return the original errata sheet to the
13	MR. ROSENBLATT: Off the record.	13	deposing attorney within thirty (30) days
14	(At 3:02 p.m. the deposition was	14	of receipt of the deposition transcript
15	concluded.)	15	by you. If you fail to do so, the
16	,	16	deposition transcript may be deemed to be
17		17	accurate and may be used in court.
18		18	and may be used in court
19		19	
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	Page 247		Page 249
1	Page 247 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER	1	Page 249
1 2	CERTIFICATE OF CERTIFIED SHORTHAND REPORTER I, PAULINE M. VARGO, a Certified	1	
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	CERTIFICATE OF CERTIFIED SHORTHAND REPORTER I, PAULINE M. VARGO, a Certified Shorthand Reporter of the State of Illinois, C.S.R. No. 84-1573, do hereby certify: That previous to the commencement of the examination of the witness, the witness was duly swom to testify the whole truth concerning the matters herein; That the foregoing deposition transcript was reported stenographically by me and thereafter reduced to typewriting under my personal direction; That the reading and signing of said deposition was reserved by counsel for the respective parties and the witness; That the foregoing constitutes a true record of the testimony given by said witness before this reporter; That I am not a relative, employee, attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action. CERTIFIED TO THIS 5th DAY OF FEBRUARY, A.D., 2016.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	ERRATA PAGE LINE CHANGE REASON: REASON: REASON: REASON: REASON: REASON: REASON: REASON: REASON:
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1	ACKNOWLEDGMENT OF DEPON		
2			
3	I,, do hereby certify that I have read the		
	foregoing pages, and that the same		
4	is a correct transcription of the answers		
5	given by me to the questions therein propounded, except for the corrections or		
_	changes in form or substance, if any,		
6 7	noted in the attached Errata Sheet.		
8 9	BRUCE ALAN ROSENZWEIG, M.D.	DATE	
10			
11 12			
13			
14	Subscribed and sworn		
15	to before me this		
1.0	day of, 20		
16	My commission expires:		
17			
18	Notary Public		
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20 21			
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1	LAWYER'S NOTES	Page	251
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